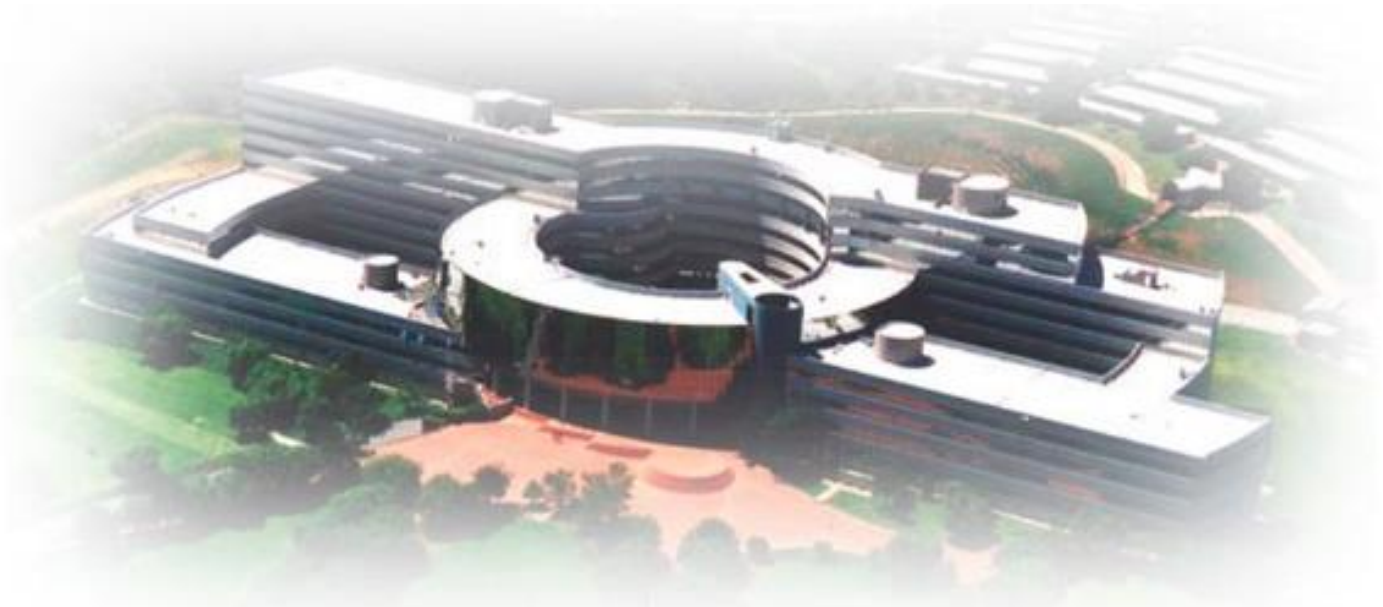


FINDINGS BY THE AGSA INCLUDING PCD CLARITY SEEKING QUESTIONS



AIM



To Brief Members of the PCD Regarding the Findings by the AGSA including the PCD Clarity Seeking Questions



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SCOPE

- Introduction
- Deployment of Soldiers
- Repatriation of RSA Citizens from Wuhan Province in China
- Misallocation of Funds
- Medicine and Equipment
- Other Log Matters



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INTRODUCTION

- The AGSA had made their findings based on four focus areas which include
 - the deployment of soldiers to various provinces to assist with enforcing law and order;
 - the implementation of additional health measures, including establishing quarantine sites,
 - laboratories and field hospitals with necessary equipment;
 - procurement of personal protective equipment (PPE)
 - and the repatriation of South African citizens from Wuhan Province, China.



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DEPLOYMENT OF SOLDIERS

- Regarding the deployment of soldiers, the audit focused on verifying the allowances paid to the deployed forces (regular and reserve members) as well as the salaries of reserve force members for the period 1 April to 31 July 2020.
- No discrepancies were noted for the period under review. However, they indicated that they will further test the deployment of soldiers for the period 1 August 2020 to 30 September 2020 as part of the normal audit process.



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REPATRIATION OF SOUTH AFRICAN CITIZENS

- The audit of the Wuhan repatriation mission focused on reviewing the procurement process for the flight and the recording of the related costs in the department's books.
- The review was completed and no significant findings were identified.



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MISALLOCATION OF FUNDS (RM34.86)

- There was initially a misallocation of the first payment for Interferon Alfa 2b, amounting to R34.8 million, which was allocated to Project THUSANO.
- This was subsequently corrected in our financial records on the 27 October 2020 and allocated to Op NOTLELA – Medicine.
- This is to confirm that the misclassification finding from the AGSA was corrected. The supporting journal and adjustment was communicated to the AGSA.



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Medicine and Medical Equipment



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No Needs Assessment Was Done Before The Drug Was Acquired (1)

- At the beginning of Covid-19 pandemic, there was no single drug that could cure Covid-19.
- All drugs were experimental and 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.



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No Needs Assessment Was Done Before The Drug Was Acquired (2)

- 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.



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WHAT WAS THE URGENCY FOR PROCURING SUCH A HUGE CONSIGNMENT AT ONCE? (1)

- The interferon and other Covid-19 related drugs were 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.



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WHAT WAS THE URGENCY FOR PROCURING SUCH A HUGE CONSIGNMENT AT ONCE? (2)

- 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.



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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 6 months for the duration of the pandemic to maintain optimum Interferon levels.
- Our active Force Members both uniformed and PSAPS, Reserve Force members and our VPA members and other SAMHS beneficiaries who will need Interferon boosting are numerically 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. However, SAMHS has to cover a total of 260 000 of its client base.



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OVER 900 000 VIALS WERE PROCURED - WHAT WAS THE RATIONALE FOR SUCH QUANTITIES?

- 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.



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HOW MUCH HAS BEEN ADMINISTERED TO DATE AND HAS IT BEEN BENEFICIAL?

- Ten (10) vials were administered on a patient, and the patient fully recovered without any complications within 7 days of its administration, in that he regained energy and symptoms disappeared.
- We regard this as beneficial.



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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.



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HOW IS THE DRUG ADMINISTERED AND STORED?

- One vial of 5MU 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.



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WAS SAHPRA APPROVAL OBTAINED PRIOR TO IMPORTATION AND TRANSPORTATION TO THE DEPOT?(1)

- 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 for Section 21 of Act 101 of 1965.
- It became apparent to the 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 in as many sectors were either shut or working with skeleton staff.



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WAS SAHPRA APPROVAL OBTAINED PRIOR TO IMPORTATION AND TRANSPORTATION TO THE DEPOT?(2)

- SAHPRA approval for importation was not secured by the DoD at the time due to the urgency to secure this medication within our borders before it goes off the shelf at the time.
- Further, 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.



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IT WAS REPORTED IN THE AGSA INTERIM REPORT AND MEDIA THAT ABOUT 40% OF THE CONSIGNMENT COULD HAVE POTENTIALLY BEEN DESTROYED?

- SAHPRA came to inspect the consignment more than once and even took samples for testing and confirmed that the medicine was not destroyed
- None of our drugs were damaged in any manner as we monitor conditions under which they are stored according to manufacturer's specifications.
- We are open to further sample testing to disprove this false and unfortunate assertion.



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THERE IS A CONCERN THAT SAHPRA DISAPPROVED OUR APPLICATION (1)

- SAHPRA was engaged several times, and 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 the basis of 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.

THERE IS A CONCERN THAT SAHPRA DISAPPROVED OUR APPLICATION (2)

- Further contact via emails and telephone calls enquiries drew blank to date.
- It was later established that communication done by SAHPRA was at an operational level and did not include relevant role-players. This is being rectified.



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HOW DOES THE SANDF INTEND TO USE HEBERON R AND WHO WILL ADMINISTER IT?

- The SANDF intends to smoothen relations with SAHPRA through dialogue and optimize communication with 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.
- Qualified medical doctors within SAMHS from the Department tasked with preventive medicine outside Hospital, will administer the drug the same way they did before with the approval of 10 vials.

WAS THERE CONSULTATION AND INTERACTION WITH OTHERS INCLUDING NDOH AND SUPPORT WITHIN SAMHS?(1)

- Two webinar clinical discussions were held with Cuban Specialist, 1 (one) 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.



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WAS THERE CONSULTATION AND INTERACTION WITH OTHERS INCLUDING NDOH AND SUPPORT WITHIN SAMHS?(2)

- 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 the development of its Clinical trials and Section 21 applications.



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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.



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WHAT IS THE PLANNED CONSEQUENCE MANAGEMENT FOR ANY LAWS BROKEN? (1)

- The investigation commissioned by the Minister will come up with concrete recommendations and where consequences/action should be taken, the Department will do so.
- In carrying its mandate to serve, it may find itself operating in a mode of survival instinct and inadvertently overlook normal peacetime procedure without any bad intention to undermine the law in expediency.



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WHAT IS THE PLANNED CONSEQUENCE MANAGEMENT FOR ANY LAWS BROKEN? (1)

- 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 on identified corrupt activities and criminalities where evidence is being collected by our Intelligence to ensure successful prosecution.



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STAND-OFF BETWEEN SAHPRA, HAWKS AND MILITARY POLICE – PMG (1)

- There was never any stand-off between SAHPRA and the Military.
- SAHPRA was allowed to enter into the unit by the Officer Commanding without any problem.
- SAHPRA requested the Officer Commanding to open the store where the medicine was kept in order to satisfy themselves on storage conditions compliance.



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STAND-OFF BETWEEN SAHPRA, HAWKS AND MILITARY POLICE – PMG (2)

- The store was opened and they did their inspection.
- They told the Officer Commanding that they were satisfied and then left the Unit.
- By the time the senior officers and Military police arrived, SAHPRA members and the Hawks had already left the unit.



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PROGRESS MADE WITH SAHPRA

- SAHPRA inspected the medical vials and their storage conditions
- The series of technical meeting at high levels were held with SAHPRA
- Corrective measures were adopted
- The medicine will only be used for clinical research trials which are randomized and controlled in nature.
- Detail approval processes for clinical research have been outlined to SAHMS which is in the process of complying with this process.



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Log Related Concerns



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CONTRACT SIGNED AFTER DELIVERY (1)

The South African Government and Cuban Government have bilateral agreement on defence to defence relationship. These contracts have been signed by a duly appointed official. Subsequent to this agreement Project THUSANO was born which facilitated services that ought to be provided to both countries on specific professional and technical services required by each country. The South African Department of Defence has contract No. TI 17-001-SUIDAFRICA to provide professional and technical services and No. TI 17-002-SUIDAFRICA to provide services of vocational training respectively with the Cuban Department of Defence.



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CONTRACT SIGNED AFTER DELIVERY (2)

The process of implementing activities and implied military operational tasks as outlined on the contracts is firstly through a meeting by both parties to agree on the related military requirements of what needs to be achieved. Secondly and based on the principle agreement between both parties, a supplement will be drafted by both parties and it will be delivered to South Africa for verification and after that counter signing will be done by delegated official, it is only then that payment process will start.



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CONTRACT SIGNED AFTER DELIVERY (4)

The contract and supplement agreements must be signed in their original form, which imply that they must be delivered from one end to the other. As a result, the Cubans had to be the first signatories before the consignment left Cuba. The original signed documents accompanied the consignment to RSA and upon arrival the other party, namely, the Department of Defence had to sign which completed the legality of the documents and the consignment.

ORDER AND IMPORTATION OF THE DRUG AND NO DOCUMENTATION FOR THE IMPORTATION OF THE DRUG(1)

The regulation of Act 101 Of 1965 Section 22 which direct processes to be followed in importing pharmaceutical product bears relevance, the SAMHS as a subsidiary of Government perceived itself not in the same light as importing pharmaceutical companies and wholesalers and its judgement thought itself exempt in military to military agreements of biotechnology product such as Interferon. This was because the Military has CBR sole capabilities in the country and therefore perceived Force Protection Interferon as not a treatment but Prophylactic biological product in Biological threat to internally deployed soldiers. This unfortunate error of judgement has been clarified with SAHPRA, ongoing inspection of integrity and use of medicine is being assured in line with legislation.



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ORDER AND IMPORTATION OF THE DRUG AND NO DOCUMENTATION FOR THE IMPORTATION OF THE DRUG(2)

Regarding the importation of the drug, it was cleared by South African Customs upon arrival at both Waterkloof and OR Tambo International Airport. Supporting documents are available in the Department.



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ORDER AND IMPORTATION OF THE DRUG AND NO DOCUMENTATION FOR THE IMPORTATION OF THE DRUG (3)

Emphasis is to be placed that there was no need for SANDF to embark on a procurement process to acquire this medical service because of its limited availability. Our bilateral agreement with Cuba was useful to address the urgent requirement.



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PROGRESS OF MINISTER'S INVESTIGATION REGARDING INTERFERON B

- The Minister of Defence and Military Veterans has signed the terms of reference for the investigation.
- A copy of which was forwarded to AGSA.
- Members of the Ministerial Task have already been appointed. What remains are administrative issues, for example, oath taking and vetting.



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CONCLUSION

- Covid-19 Presented new challenge 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.



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CONCLUSION

- 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.



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Questions/ Comments