Notes on the draft AstraZeneca Agreement:

Para 2- Government would need to ensure that it is completely ready to effect payment as stipulated, within the required timeframes, and ensure that there are not any delays. Will need to ensure that full payment can be effected upon receipt of the invoice, so that would be within a very few days after the contract is signed.

Para 3- should refer to "O. R. Tambo International Airport", not "Johannesburg International Airport".

Para 3.6 to 3.8- It would be necessary to be very mindful of the tight timeframe of 24 hours for reporting any patent defects, and the 7 day period for reporting latent defects in the virus. Is there sufficient clarity regarding what would be considered to be "latent defects", and at what stage would they be considered to be "discoverable". If, for some reason, there was a vaccine shipment that was defective that rendered it ineffective, but did not produce, for example, an adverse reaction or something. When would that be "discoverable"? Perhaps it would be helpful to ensure that the understanding of "latent" and "patent" defects is clearly and consistently understood by both parties, and if necessary, perhaps defined.

Should the liability for latent defects be limited to replacement with new doses of the vaccine? What about other effects or damages that might be suffered? This is likely covered by Paragraph 10, which is considered below.

Ensuring the cold storage chain correctly at all times will be critical, failing which any issues regarding the vaccine would not be able to be addressed through obtaining replacement vaccine under the contract.

Paragraph 6.1- It is proposed that the second sentence of the paragraph should perhaps be clarified to read, "The DoH will make an application to the South African Health Products Regulatory Authority (SAHPRA)in terms of section 21 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), for the sale and use of the said Vaccine.". Also similarly applis to section 1.3.

Paragraph 7- Government must be able to comply with the specified roll out requirements. Of particular importance are provisions relating to adverse reactions and recalls. Why should the DoH require prior approval from the Serum Institute to recall the vaccine? If there is a serious emergent situation that arises that requires urgent action to prevent further damage, issues, harm to patients, etc., the DoH should be able to act urgently if a crisis arises. Cost implications relating to a recall should be noted. The reference to "Johannesburg International Airport" should be changed to "OR Tambo International Airport".

7.6. DOH undertakes and agrees to notify Serum any change or modification in the regulatory provisions or guidelines applicable to the said Vaccine in South Africa. In case the said Vaccine is recalled due to change in the regulation or applicable laws in South Africa relating to the Regulatory Approvals, then DOH shall bear entire cost of such replacement. However, if such recall or change is due to guidelines of World Health Organization (WHO), then Serum shall bear entire cost of a replacement to DOH.

7.7. DOH will not recall the said Vaccine from the market without obtaining Serum's prior written consent. DOH shall be solely responsible at its own cost and expenses for recall of the said Vaccine at any time, if such recall is due to defective storage by DOH or handling of the said Vaccine before delivery/transfer to DOH designated warehouses by DOH, and DOH shall accept any liability arising from or due to such recall.

Serum shall be solely responsible at its own cost and expenses for recall of the said Vaccine at any time, if such recall is due to defective manufacture, storage or handling of the said Vaccine by Serum until delivery at Johannesburg International Airport per the agreed CIF Terms, and Serum shall accept any liability arising from or due to such recall.

Paragraph 8- Intellectual Property- Just to note, SA has made calls that intellectual property rights in respect of CoVID vaccines should be waived, but it is noted that this is likely a "take it or leave it" clause in respect of finalising the agreement.

Paragraph 9- "9.3.5 title and risks to the delivered said Vaccine shall pass on to DOH upon delivery to DOH on CIF, Johannesburg International Airport in accordance with Incoterms 2020."

Note that effectively, this agreement seeks to make virtually anything that might happen in relation to the vaccine subsequent to delivery, the responsibility of the DoH.

Clause 10- The Serum Institute of India would be liable if there was misconduct or gross negligence in relation to the manufacture of the vaccine, while the DOH would be liable for any misconduct or gross negilence arising from its handling and administration of the virus. This seems to be understandable. The wording of paragraph 10.2 subparagraph (c) is concerning, as it seems possible to interpret it that any claims for physical injuries and death and similar losses arising from the administration and use of the vaccine that was received by South Africa, the Department of Health would be liable for. Paragraph (c) should be clarified to exclude any proven third party claims, suits, losses, damages, costs, fees and expenses which results solely from the proven gross negligence or proven wilful misconduct by the supplier with regard to the manufacturing, administration or use of the vaccine. For instance, if Serum provided incorrect information regarding the appropriate administration and use of the vaccine, it should be responsible for that.

The last sentence in paragraph (c) is also concerning:

> "Such indemnification will be available regardless of where the said Vaccine is administered, where the claim is brought, and whether the claim of a defect originates from the distribution, administration and use, clinical testing or investigation, manufacture, labelling, formulation, packaging, donation, dispensing, prescribing or licensing of the said Vaccine in South Africa.".

So once the vaccine is delivered to South Africa, the Government is pretty much liable for whatever happens in relation to its administration or use, regardless of where that happens, for instance, even if the administration or use ended up not being within South Africa.".

Paragraph 10.3. "Except as otherwise expressly set forth in this Agreement, and to the maximum extent permissible under the applicable laws, Serum makes no representation and extends no warranties of any kind, either express or implied, regarding merchantability of the said Vaccine or fitness of the said Vaccine for a particular purpose."

So effectively, Serum cannot be held responsible for any representations regarding the effectiveness of the vaccine. This is very important to note.

Paragraph 11.2- the following provision should be noted and queried:

> "Further, if the manufacturing is prevented or delayed by a Force Majeure event, then Serum shall not be obligated to refund the equivalent of the advance payment that has not been supplied as the said Vaccine to DOH due to such Force Majeure.".

Why should not the Serum Institute of India not be required to refund the advance payment if it cannot perform and supply the vaccine due to Force Majeure?

Paragraph 12.2.2- Does this provision overly impede the ability of the DoH to be appropriately transparent to the public in relation to the vaccine and its administration, if consent of the Serum Institute to publish any data is required?

Para 13.2.2- Important to note, that if there is a breach of the Agreement by the DoH, the advance payment would be forfeit.

Para 13.3- Note that the Serum Institute can cancel the Agreement for any reason on 15 days' notice, not only for breach of contract.

Para 14.2.1- Note that on termination, all regulatory approvals and files would be required to be returned to the Serum Institute.

Para 14.2.2- Government should take cognizance of this provision, and the potential for claims by Serum:

"DoH would on termination not be entitled to any compensation or damages or other payment whatsoever, whether in respect of goodwill or loss of profit. For avoidance of doubt, it is clarified that the Serum shall be entitled to damages for breach of any obligations, representations, warranties or covenants under this Agreement including other payments whatsoever as provided in this Agreement.".

Paragraph 20- Note that the law of India would govern the Agreement, and legal disputes regarding the Agreement would need to be lodged in Pune, India.