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## RT298-1-2025 NOTICE TO BIDDERS 1

## BID RT298-1-2025: SUPPLY AND DELIVERY OF PHARMACEUTICAL MATERIALS TO THE STATE FOR PERIOD ENDING 29 FEBRUARY 2028

## QUESTIONS AND ANSWERS DURING THE NON-COMPULSORY BRIEFING SESSION

#	QUESTIONS	ANSWERS
1.	Is a SAHPRA license from the manufacturer enough?	Bidders must submit a license for manufacturing, importing, distributing, and or wholesaling of medical devices and IVD's issued by SAHPRA (South African Health Products Regulatory Authority).
	Is SAHPRA mandatory or not in this contract?	As a supplier it is your responsibility to verify with SAHPRA which items require a licence and determine their respective classification categories.
2.	Do we need to submit Annexure D & E for declaring Local Content?	The bidder must declare the local content percentage under column L in Annexure B (Pricing Schedule). Note that Annexures C and D are no longer applicable due to revised regulations.
		Refer to paragraph 6.5.2.6 (d) of the Special Conditions of Contract.
3.	Why under Quality Assurance requirements are only two (2) ISO Certificates acceptable?	Bidders are required to submit a valid quality assurance certificate, such as ISO 13485 or ISO 9001 and an equivalent certificate relevant to pharmaceutical material.
4.	If items do not have brand name like cartons (RT298-04-005) do, we leave it or indicate not applicable? On the pricing schedule?	Your manufacturer should provide you with the brand names of the products they offer.
5.	In terms of the samples, will be an actual sample of what is going to be submitted or can one make a mock-up sample if its not:	The sample offered should be a true reflection of the products you are going to supply at heath facilities if you are awarded the bid.
6.	Should our pricing include delivery to provinces that are not participating?	Prices quoted must be furnished based on delivered to State facility country-wide inclusive on VAT.
7.	I requested a quote for SABS for the items that need testing. Below is the response from SABS	Where specified in the technical specification, the bidder to supply material specification from the manufacturer.

Nkwama wa Tiko • Gwama la Muvhuso • Nasionale Tesourie • Lefapha la Bosetšhaba la Matlotlo • uMnyango wezezimali • Litiko leTetimali taVelonkhe • Tirelo ya Matlotlo a Bosetšhahaba Tshebeletso ya Matlotlo a Naha • UMnyango weziMali • Isebe leNgxowa Mali yeLizwe



#	QUESTIONS	ANSWERS
	"On this list, there is no reference to SANS standards or any testing requirement, and the Packaging laboratory will not be involved in testing of any of these products".	Where specified the requirements are stated e.g. thickness ≥ 60 micron etc. The bidders must provide a certificate of conformity or analysis to verify compliance.  The detail specification will provide for information. This is not referring to SANS standards.
8.	Does the Amber bottle cap require a gasket lid, Thermal sensitive and sub sensitive, PE seal with	Standard screw cap - No Gasket lid, Thermal sensitive, sub sensitive and PE required.

Regards

**BRENDA MASHIFANE** 

For CHIEF DIRECTORATE: TRANSVERSAL CONTRACTING

OFFICE OF THE CHIEF PROCUREMENT OFFICER

**DATE: 22 APRIL 2025** 

