



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

**ADDITIONAL QUESTIONS AND ANSWERS – BRIEFING SESSION 12 JULY 2024
BIDS HP01-2025TB, HP02-2025AI AND HP13-2025ARV**

No.	Question	Answer
1	<p>We are completing the tender documents and get the below error.</p> <p>Could you please assist with the password?</p> <p>or</p> <p>Struggling to complete the PDF electronically as per usual practice (or in the past).</p>	<p>The bid documents should be printed and completed by hand. The SBD documents are not fillable PDF documents.</p> <p>The only fillable documents are the excel spreadsheets.</p> <p>You do not need a password to download or print the bid document.</p>
2	<p>Could you please confirm if we can use electronic signatures to sign the bid documents? In several instances the person can only sign electronically as they may be traveling or not available at the time,</p> <p>We are mainly looking at the authority to sign bids document,</p> <p>Also, regarding the Declaration of Compliance with GMP (PBD 5) and PBD 8, can the individual given the authority to sign the bids sign these documents or does it only have to be the CEO?</p> <p>We seek to understand as the individual has been given authority to sign the bids.</p>	<p>The resolution/authority to sign bids letter that has been signed electronically by authorized personnel is acceptable.</p> <p>The CEO should preferably sign the GMP (PBD 5) and PBD 8. However, if the CEO is unavailable, authorized personnel listed in the Bid Signature Resolution/Authority (BSRA) may sign these documents if permission for them to do so is explicitly indicated.</p>
3	<p>Please advise, is it ok to submit a fridge item without a cooler as a sample?</p>	<p>Fridge items can be sent via Cold Chain or Non-Cold Chain delivery. The delivery box must be labeled as a "Fridge Item".</p>
4	<p>Please advise where tender samples for HP02-2025AI should be delivered in Gauteng and Cape Town.</p>	<p>Refer to the SRCC 6.5 for the address and contact information of both health institutions.</p>
5	<p>Kindly email me the tender forms and the debriefing dates for the above tender.</p>	<p>The documents you require are available on the National Departments website:</p>

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		<p>www.health.gov.za under Pharmaceutical Tenders.</p> <p>You will find all downloadable files under the Pharmaceutical Tenders tab.</p> <p>The briefing session was held on the 26th of July 2024. The presentation of the briefing session is available on the NdoH website.</p>																								
6	<p>Kindly advise if we can submit bid on item no 15 as our Linezolid 600mg has 10 tablets.</p> <table border="1" data-bbox="199 600 798 1048"> <tr> <td style="text-align: center;">15</td> </tr> <tr> <td style="text-align: center;">Linezolid 600mg, 28/30 tablets</td> </tr> <tr> <td style="text-align: center;">Pack of 28/30 tablets</td> </tr> <tr> <td style="text-align: center;">112,298</td> </tr> </table>	15	Linezolid 600mg, 28/30 tablets	Pack of 28/30 tablets	112,298	<p>Bidders are encouraged to submit bids according to the advertised specifications. However, if your bid includes any deviations, please clearly state the nature of the deviation on the Bid Response Document.</p>																				
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7	<p>Can a product be submitted without the outer carton and with only 10% leaflet. Can we apply the same to all the other products on the ARV Tender?</p>	<p>In accordance with GCC/SRCC, submitted samples must accurately represent the final product to be supplied, including the label, carton, package insert (PI), and any other packaging components.</p>																								
8	<p>Concerned about how we ensure protection of sensitive financial information in the excel doc.</p> <p>How does the tender team ensure that such information is kept confidential and not shared with competitors.</p> <table border="1" data-bbox="199 1512 813 1713"> <tr> <td>% of Delivered Price attributable to API</td> <td></td> </tr> <tr> <td>Local (API/Raw Material)</td> <td></td> </tr> <tr> <td>Imported (API)</td> <td></td> </tr> <tr> <td>% of Delivered Price attributable to Formulation</td> <td></td> </tr> <tr> <td>Local (Formulation)</td> <td></td> </tr> <tr> <td>Imported (Formulation)</td> <td></td> </tr> <tr> <td>% of Delivered Price attributable to Packaging</td> <td></td> </tr> <tr> <td>Local (Packaging)</td> <td></td> </tr> <tr> <td>Imported (Packaging)</td> <td></td> </tr> <tr> <td>% of Delivered Price attributable to Logistics</td> <td></td> </tr> <tr> <td>% of Delivered Price attributable to Gross Margin</td> <td></td> </tr> <tr> <td>Currency</td> <td></td> </tr> </table>	% of Delivered Price attributable to API		Local (API/Raw Material)		Imported (API)		% of Delivered Price attributable to Formulation		Local (Formulation)		Imported (Formulation)		% of Delivered Price attributable to Packaging		Local (Packaging)		Imported (Packaging)		% of Delivered Price attributable to Logistics		% of Delivered Price attributable to Gross Margin		Currency		<p>All information submitted in the bid documents is treated as confidential and is solely for the purpose of evaluating the bids. The information is accessible only to the relevant committees and is not shared with any individuals or stakeholders outside of those committees.</p>
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9	<p>Ofloxacin is both in the class category with more quantities and the second on its own with fewer quantities than the class.</p>	<p>Item 130 will be evaluated within a therapeutic class for both paediatric and adult use, where higher quantities are required. If Item 130 is not recommended for award within this therapeutic class, the standalone Item 131 will be</p>																								

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	<p>Why is it like that and does it mean one can submit two bids, one for item 130 number and the other one for item 131?</p>	<p>recommended for award, as it requires a smaller volume for paediatric use. If Item 130 is awarded within the therapeutic class, Item 131 will be cancelled, and its volumes will be transferred to Item 130. Bidders are therefore advised to place bids on both items.</p>
10	<ol style="list-style-type: none"> 1. We intend to make use of an electronic Professional Information, in alignment with Regulation 11 of the Act, whereby the electronic PI can be accessed via a QR code included on the Patient Information Leaflet and possibly the direct product label. Is this acceptable for the tender products? 2. As part of the sample submission requirements, we are required to include a copy of the current SAHPRA Professional Information with the sample. As mentioned in point 1 above, we intend to make use of an electronic Professional Information, which may be accessed via a QR Code. Would it thus be acceptable to include a loose Professional Information together with the sample? 3. Is it a requirement for the Patient Information Leaflet to be attached to the product container (the SAHPRA approved product container comprises an HDPE plastic bottle with polypropylene plastic screw tops only, i.e. there is no carton as secondary packaging). Must we thus affix the SAHPRA approved Patient Information Leaflet at the time of supplying product, or is there an allowance to include the Patient Information Leaflets as separate documents with the product in the shippers, whereby we would include one Patient Information Leaflet with each product container in each shipper? 	<p>Kindly note as per our SRCC the original Package insert is required and no QR code will be accepted.</p> <p><u>As part of the Bid submission:</u> <i>“Original Package Insert (PI) or document detailing professional information approved by the Medicines Control Council (MCC) or the South African Health Products Regulatory Authority (SAHPRA) for each product offered. Note: All PI’s must be marked with the relevant item number and be sorted and filed/submitted in numerical order.”</i></p> <p><u>As part of the Sample Submission</u> <i>“All samples submitted must include an eligible package insert or document detailing professional information approved by SAHPRA.”</i></p> <p>If the product is in a container without an outer carton the Package Insert must be attached to the container.</p>
11	<p>The below products are not appearing on the bid.</p> <p>Amoxicillin and Clavulanic Acid for suspension 250mg and 62,5mg/5ml; 100ml NSN number 180002786 and</p> <p>Amoxicillin and Clavulanic Acid for suspension 125mg and 31,25mg NSN number 180002781</p>	<p>The Pediatric STGs and EML recommend the use of an amoxicillin/clavulanic, oral in a ratio of 14:1. The previously awarded products on tender had higher clavulanic acid, with a ratio of amoxicillin/clavulanic acid of 4:1. This higher dose of clavulanic acid leads to more adverse events including nausea and vomiting, which negatively impact the patient care, and can lead to non-adherence.</p>

No.	Question	Answer
		<p>The amoxicillin/clavulanic acid 14:1 ratio allows for an effective dosing with less adverse effects and is thus preferred.</p> <p>Therefore, these products have been removed from tender and replaced by:</p> <p>Amoxicillin and Clavulanic Acid for suspension 600mg and 42.9mg per 5ml suspension, 100ml and, Amoxicillin and Clavulanic Acid for suspension 600mg and 42.9mg per 5ml suspension, 50ml</p>
12	<p>However, having looked at the SEP incl VAT value of the said items, this is a R90k+ total of samples to be sent.</p> <p>With that in mind, please advise if we can send pack shots, empty packs and Package inserts to the samples departments will this suffice?</p>	<p>No, the sample submitted must be a true representation of what will be provided, as stated in SRCC Section 6.5. Expired stock will also be acceptable for sample submissions.</p>
13	<p>Could the NDoH consider the submission of HP13-2025ARV, HP02-2025AI and HP01-2025TB for a later date?</p>	<p>No, tender life cycle scheduling does not allow for any extension currently.</p>
14	<p>The above tender closes at 11.00 on Monday, 09 September 2024.</p> <p>Please advise if tender bids can be submitted over a weekend i.e., will the building in which the tender box is situated be open over a weekend in order to submit the bids, and if yes, what are the times that the building will be accessible.</p>	<p>The tender can be submitted at any time, during working hours (Monday to Friday) Time: 07.30 – 16.30pm</p>
15	<p>Kindly provide clarity with reference to SBD 6.1 on the specific goals as the sub-minimum % are not indicated/imposed for compliance to the 4 requirements. We need to know how to translate our compliance status for the below requirements:</p> <ol style="list-style-type: none"> 1. Ownership by Historically Disadvantaged Individuals – maximum 4 points. 2. Ownership by women - maximum 2 points. 3. Ownership by people with disabilities - maximum 2 points. 4. Ownership by South Africans (or development of locally (SA) owned 	<p>Preferential points under SBD 6.1 are allocated based solely on the ownership held by Historically Disadvantaged Individuals (HDI) and South African citizens within the bidding enterprise. The allocation of points in each section is directly proportional to the percentage of ownership, as supported by valid documentation such as share certificates.</p> <p>Here is how the points allocation works:</p> <ol style="list-style-type: none"> 1. Ownership by Historically Disadvantaged Individuals – Maximum 4 Points The percentage of HDI ownership in the

No.	Question	Answer
	enterprises in the bid itself) - maximum 2 points.	<p>bidding enterprise will translate into the same percentage of the available 4 points. For example, if the enterprise has 50% HDI ownership, 50% of the 4 points (i.e., 2 points) will be allocated.</p> <p>2. Ownership by Women – Maximum 2 Points Similarly, the percentage of ownership held by female South African citizens will determine the proportional allocation of the 2 available points.</p> <p>3. Ownership by People with Disabilities – Maximum 2 Points The same calculation applies to ownership by people with disabilities. The percentage of ownership will determine the allocation of points from the available 2 points.</p> <p>4. Ownership by South Africans (or Development of Locally Owned Enterprises) – Maximum 2 Points For this section, the percentage of ownership held by South African citizens, both HDI and non-HDI, will translate into points. All ownership claimed in the sections above will automatically contribute towards the "RDP Goal."</p> <p>Please note that no points are allocated for any other criteria besides the actual ownership held.</p>
16	Could you please confirm for me if the suggested reference price is VAT included.	<p>As per section 5.2 of the SRCC</p> <p><i>"The prices quoted must be furnished as all inclusive (incl. VAT) based on supply and delivery."</i></p> <p>The Reference Prices published is also VAT inclusive.</p>
17	I would like clarity on the SBD 5 NIPS obligation document which we are required to complete for this tender.	<p>The obligation document that should be completed (SBD5) must be sent with the reporting template to the Department of Trade and Industry (DTI) within 5 working days after award.</p> <p>Kindly contact DTI to obtain the reporting template.</p>
18	Kindly please assist with the product sample submission date for HP02-2025AI.	<p>The samples for items on HP02-2025AI could be submitted at any time, during working hours, to both health institutions before the closing time and date of the tender.</p>

No.	Question	Answer
		Samples submitted after 11h00 on 09 September 2024, will be considered as late and will not be evaluated.