health
Department:
Health
REPUBLIC OF SOUTH AFRICA

QUESTIONS AND ANSWERS – BRIEFING SESSION 26 JULY 2024
BIDS HP01-2025TB, HP02-2025AI AND HP13-2025ARV

No.	Question	Answer
1	Should Set 2 and Set 3 be on the same or separate flash drives?	We prefer that set 2 and 3 be submitted in one flash drive.
2	Do SAHPRA approved Package Insert (PI) in A4 format need to be certified, and if so, can it be limited to the top page as suggested in a previous briefing?	There is no need for the SAHPRA approved Package Insert to be certified.
3	Do we need to supply the Patient Information Leaflet?	Yes, bidders are still requested to submit a Patient Information Leaflet.
4	With regard to License to Manufacture and Medicine Registration Certificates and Tax PIN, all of which are received by e-mail, a commissioner of oaths will sign the printed version if shown the e-mail from SAHPRA or SARS. Will it be acceptable?	Yes, it will be acceptable.
5	Kindly confirm if Raltegravir is now excluded from the specs.	We can confirm that the following three products listed are not on the specification list and therefore, will be excluded from the HP13-2025ARV tender. Raltegravir; 25mg; Tablet; 56 Tablet Raltegravir; 100mg; Tablet; 56 Tablets Raltegravir; 400mg; Tablet; 56 Tablets Should this product be required for use from July 2025, the institutions that need the products, will procure it through Request for Quotations (RFQ). You are encouraged to familiarize yourself with the 2023 ART Clinical Guidelines published in April 2023 and available on the National Department of Health Website. The compilation of the specification list is informed by the updated guidelines.
6	We note that, although the RFP (page 64) refers to the possibility of the products to be supplied pursuant to the RFP being imported, slide 10 of the Presentation: - Refers to a "licence to manufacture or import, distribute medical devices" in the context of the supply of a medical device; however,	The slide presentation was a summary of the requirements. Emphasis was placed on the Medical Devices and Complementary medicine licences as they have been updated in the SRCC with new SAHPRA requirements, whereas the Licence to Manufacture for medicines has been

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	- When it refers to the licensing requirement for medicines it refers only to a "licence to manufacture medicines" and not to a licence to import or distribute medicines. It is not clear whether this distinction was made purposefully or is simply a function of the slide setting out a summary of the requirements in which the reference to licences to import and/or distribute medicines have inadvertently been omitted. Can you please confirm that imports will also be permitted in respect of the medicines to be supplied to the DOH pursuant to the RFP?	in use for years and no additional SAHPRA changes have been implemented. Refer to Section 6.1 of the SRCC regarding licence requirements. The licence to manufacture (import/export) as approved by SAHPRA in terms of section 22C(1)(b) of the Medicines Act must be submitted in the bidder's name. There are no medical devices or complementary medicines in the three tenders advertised.
7	It is our understanding that, if some or all of the products in respect of which the bidder submits a bid will be manufactured by a party other than the bidder (e.g., another group company or a third party): a. It is not required that the bidder holds a manufacturing licence or that the manufacturer participates in the RFP as a joint venture or consortium member; and b. For purposes of a compliant bid, the documentation which must be submitted comprises: i. A certified copy of the manufacturer's manufacturing licence only if the products are manufactured locally; ii. A completed and signed PBD1 executed by or on behalf of the bidder; and iii. A signed Authorisation Declaration (PBD1.2) executed by or on behalf of such manufacturer. Can you please confirm whether this understanding is correct?	In all cases, it is required that the bidder must be the applicant on the Licence to Manufacture (refer to Section 6.1 of the SRCC for requirements of the Licence). The bidder must also be the applicant on the medicine registration certificate (refer to section 6.2 of the SRCC for the requirement of the medicine registration certificate). Where the bidder is not the applicant on the medicine registration certificate, refer to section 5.2.1 of the SRCC for Joint Venture/Consortium requirements. In such a circumstance, both the bidder and the applicant must have a Licence to Manufacture, and both must be submitted with the bid. Where the bidder is the applicant, a joint venture or consortium agreement is not required for third party manufacturing. If the medicine registration certificate specifies a third-party manufacturer that is not the bidder/applicant, the third-party manufacturer for the bidder/applicant should complete the PBD1.2 and must be submitted with the bid. For each item where the manufacturing site differs per medicine registration certificate (refer to section 6.4 of the SRCC), inclusive of any additional third-party documentation that may be required. To qualify for preference of locally produced products, the local manufacturing site must be

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		indicated on the medicine registration certificate, the License for this site must be provided (refer to section 6.1 of the SRCC), and the PBD1.2 must be completed for each item. In the event the manufacturing site differs per medicine registration certificate (refer to section 6.4 of the SRCC), a PBD1.2 must be completed by the manufacturing site and submitted with the bid. In these circumstances, the bidder and the local manufacturing site must both have a License to Manufacture, and both must be submitted with the bid.
8	In terms of the specific goals set out in the RFP ("Specific Goals"), in order for the bidder to receive points for the percentage ownership of the bidder held by a person with a disability, such person must be a historically disadvantaged individual (as defined in the RFP) ("HDI") as well (page 71 of the RFP). The Presentation, however, does not include the requirement that the person must be an HDI as well, i.e., it refers only to a person with a disability. In order for ownership by a person with a disability to qualify for the purpose of the Specific Goals, must the person also be an HDI?	Any South African citizen with a disability supported by a medical certificate, detailing the nature and extent of the disability, is defined as an HDI for the purposes of allocating preferential points on the SBD6.1 claim. Furthermore, the percentage equity ownership of such an individual can also be included in all other sections of the SBD6.1 claim (excluding preferential points claimed for female ownership, where such owner with a disability is not female). In all cases, the percentage ownership in the bidding enterprise must be substantiated with share certificates in the name of such an individual.
9	During the Briefing Meeting, you confirmed that the DOH would recognize an ownership interest in respect of the bidder which is held by a third party (who may not be an HDI) on behalf of an HDI, provided that the connection between the third party and the HDI is substantiated.	During the briefing meeting, the NDoH referred to conditional recognition of ownership related to a third party and referenced scenarios where the third party may be a legal entity or individual in compliance with the criteria of HDI ownership. Specifically, if a bidding enterprise does not have any HDI ownership and seeks recognition for HDI ownership vested in the co-ownership of a third party in the bidding enterprise, this must be substantiated by share certificates. In another scenario where the third party is a Trust with ownership in the bidding enterprise, such ownership must also be substantiated with share certificates and aligned with all SRCC stipulations. HDI Beneficiaries identified must also be Trustees of the Trust and actively involved in the management of the Trust.

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		Ownership held through a third party is only recognised if it aligns with the recognition criteria described above and in the SRCC is substantiated by share certificates.
10	For purposes of the RFP, if: - The bidder entered into a subscription agreement with one or more third parties (who would qualify for purposes of the Specific Goals, i.e., they are either HDIs, females and/or have a disability) in terms of which the consideration for the shares issued to them is not realizable at the time of the subscription for the shares but only at a later stage; (i.e., the subscriber will be the beneficial owner of the shares). Would the DOH recognize such ownership as being held by an HDI, female and/or person with a disability, as applicable, for purposes of determining the points related to the relevant Specific Goals?	The NDoH will not recognize such ownership for the purposes of preferential points claimed on SBD6.1.
11	Our understanding is that the Specific Goal set out in paragraph 7.1.3.1 (on page 72) of the RFP does not include any HDI criteria but applies to all South African owned enterprises. Please confirm that this understanding is correct?	HDI criteria do not apply. Therefore, all South African citizens with ownership substantiated by share certificates will qualify.
12	Based on the requirements of the RFP, we understand that the bidder is required to provide supporting evidence of the direct South African ownership in the bidder claimed in SBD6.1 only. Is this correct?	Supporting evidence for ownership held in the bidding enterprise is required for all claims made in SBD6.1, including direct and/or indirect ownership. Direct ownership must be substantiated (supporting evidence) through share certificates held by the qualifying individuals (owners) in the bidding company, aligned with the requirements of each section on the SBD6.1. Indirect ownership relates to ownership held indirectly by a legal entity and co-owner of the bidding company. Where the legal entity is owned by qualifying individuals (South Africans) and percentage ownership by these qualifying individuals are included in the calculation of preferential points (for the RDP Goal section) of the SBD6.1 claimed by the bidding company.

No.	Question	Answer
		And/or, where such legal entity is owned by qualifying individuals (HDI/Female/Disability) and percentage ownership by these qualifying individuals are included in the calculation of preferential points for HDI sections of SBD6.1 claimed by the bidding company.
13	Is it a requirement that the bidder must be registered as a VAT vendor at the time of submitting a bid in response to the RFP or with effect from the date of the contract forming the subject matter of the bid becoming effective?	The bidder must be registered as a VAT vendor from the date the contract forming the subject matter of the bid becomes effective.
14	In the event of the bidder being a consortium / joint venture - Our understanding is accordingly that, if the consortium/joint venture comprises multiple members who would contribute to the points awarded for the Specific Goals, only one of the members' credentials will be taken into account when evaluating the consortium/joint venture's bid response (e.g., if the consortium has two members who are HDIs, only the ownership interest held by one of them will be recognized). Is this correct?	Combined percentage ownership, held by all qualifying HDI`s within the nominated partner of the JV, will be recognised for preferential points as stipulated in SRCC, and if claimed in the applicable section of SBD6.1.
15	In circumstances where the bidder is an unincorporated joint venture, will it be sufficient if one of the joint venture partners holds a licence to import and/or distribute the relevant products (in circumstances where the other joint venture partners may not hold such a licence as they perform a different function in relation to the joint venture, e.g., providing resources to the consortium and/or performing functions which enable the supply of the products to the DOH)?	No, all partners of an unincorporated joint venture will be required to hold licences/registrations as required and listed in the SRCC section 5.2.1 and section 6.1. It should be noted that the partners of an unincorporated joint venture should consist of a bidder (Licence to Manufacture) and an applicant (Licence to Manufacture AND MRC holder)
16	SRCC indicates that "A Consortium / Joint Venture may, based on the % of the contract value managed or executed by their HDI members, be entitled to equity ownership in respect of HDI". By way of example, if an HDI member of the consortium does not itself supply any of the required products to the DOH pursuant to a licence but provides resources to the consortium and/or performs functions which enable the supply of the products to the DOH by the consortium, how will the percentage of the "contract value managed or executed" by such HDI member be determined?	Should the unincorporated joint venture comply with all requirements stipulated in the SRCC, the percentage (%) ownership held (and supported by share certificates) by qualifying HDI owners within the nominated partner of the joint venture to be evaluated for preferential points, will be recognized in proportion/relation to their percentage ownership held in the joint venture partnership.

No.	Question	Answer
17	Could the NDoH consider the submission of HP02-2025AI and HP01-2025TB for a later date?	No, tender life cycle scheduling does not allow for any extension at this time.
18	Could we submit expired samples, if yes by how much time can it be expired?	Yes, expired samples may be submitted, providing it is a true representation of the product which will be supplied.
19	Could you please be so kind as to send me a link to download the video recording of the briefing? Slides for the presentation?	The recording is for departmental use only, however the presentation is available on the NDoH website.
20	If a product is out of stock at the time of sending through the samples to the two depots, can a letter be sent to the depot advising that the product is out of stock and as soon as the stock is received back into the market, the samples will be sent to the depot.?	No, a true representation of the product (even if expired) must be submitted before bid closure to both facilities specified in the SRCC, before 11:00 on 9 September 2024.
21	Kindly please assist with the product sample submission date for HP02-2025AI.	Samples must be submitted before bid closure to both facilities specified in the SRCC, before 11:00 on 9 September 2024
22	If the product does not have an SEP as yet, (but has a tender price), will the bid be disqualified?	No, the bid will not be disqualified, it will be reviewed.
23	Are public shares also recognized?	In relation to SBD6.1 HDI and RDP Goal claims, public shares are not recognized. Note: It is quite common for non - South African individuals to invest in South African companies through public shares / stock market. Shares are recognized when presented in the names of HDI`s and South Africans, together with proof of the percentage ownership represented by the share certificates held by the HDI`s and South Africans pertaining to the various sections of the SBD6.1 claim.
24	If a variation for registration of a local manufacturer for the tender product has been submitted with SAHPRA but approval not yet received, can either a Proof of submission of the local manufacturer with SAHPRA be provided together with the Medicine Registration certificate, or Can a summary be created in SAHPRA DVP portal and provided together with the proof of submission of the variation as an addendum to the Medicines Registration Certificate?	No, only approved variation summary will be considered from SAHPRA with a Medicine Registration Certificate

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25	If manufacture of a product for Global fund donations (e.g. Dolutegravir/Lamivudine/ tenofovir example) is partly done in a site with WHO PQ approval and the intermediate further processed in a local site where WHO PQ is not yet in place, will it be eligible for donation stock?	No, Donation stock may only be procured from WHO Prequalified site.
26	Please provide clarity on the options for supply packs 28's, 56's, 84's called for on certain items, whereas other items such as Dolutegravir 50mg only provides option 30's.	The 28-day pack size is currently being phased out. Pack sizes suitable for a 30-day treatment cycle are required for chronic conditions. For the sake of fairness, multiples of 28's and 30's will be considered for items as indicated. For Dolutegravir 50mg market analysis shows that only a pack size of 30 is registered, however should a bid be placed for a pack size of 28's, it will be considered. Please refer to section 21 of the SRCC.
27	Regarding the estimated quantities can DOH formally share the estimates from each procuring Authority that was used to reach published estimated quantity.	Estimates are not formally shared, however can be made available to the successful supplier. After contract award.
28	Where documents are provided electronically or off a website e.g. MRC's and Tax Compliance and CIPC Documents - are these still required to be certified? SAHPRA do not issue original MRC's any longer	All hardcopy documents received from SAHPRA must be certified. Also refer to question 4. Where documents are provided electronically or off a website, they do not need to be certified. For Tax Compliance a pin must be submitted.
29	If a product is undergoing a name change at the time of bid submission can proof of submission be submitted and name approval provided later? The name may be different from that submitted on the bid document to that when ready to supply.	The MRC, Sample and Bid Response must be a true representation of the products offered. If a brand name change is approved after bid closure, and the supplier is successful updated legislative documentation will be requested, Package Insert and updated samples to be submitted.
30	Will the DOH take into account and recognize the beneficial owners?	Refer to Question 10 and response.
31	What points will be allocated to local manufacturing?	Local Manufacturing is not part of SBD 6.1 claim for preferential points, it refers to local ownership of enterprises. During the evaluation process the suppliers of "Locally produced products" will receive preference.
32	The current Final Bid Pack document is password protected compared to previous tenders, please kindly advise if we are	The Final Bid pack is password protected to ensure bidders do not make any changes to the documents. You are therefore only able to

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	expected to complete the document manually, i.e handwritten or if you are able to provide a password for the document in order to complete it electronically.	download the final bid pack and complete it manually. Please refer to paragraphs 5, 11 and 10 for the Special Conditions of contract on how to complete your bid successfully.
33.	During the briefing when the HDI section was being discussed, it was mentioned that the documentary proof for gender and ownership would be the copy of the share certificate. I can understand this when the entity is a registered (Pty) Ltd company but if there is only one shareholder in a close corporation (CC) and this person's details is on the CK documents, there would not be a share certificate FOR CLOSE CORPORATIONS. Previously the certified BBEE affidavit was given in our submissions. In this case for this tender what document would the department require to substantiate ownership and gender whilst this information is already captured on the CSD portal?	In terms of proof for shareholding, your CIPC Certificate of Incorporation (CK1) or if amended (CK2), typically identifies the % shareholding of members and can thus be submitted as proof for percentage ownership. Kindly follow the guidance of SRCC in terms of all supporting documents required in support of preferential points claimed, in each section on the SBD6.1 for the HDI, Gender, Disability and RDP Goal claim. The same % HDI ownership can also be used for RDP ownership and Gender ownership and Disability ownership - if applicable, and where there is a single owner. The ID document required, will clarify any issue regarding gender and should also be aligned with the PBD9. Furthermore, a doctor`s note will clarify disability, and a South African ID document will clarify RDP In all instances preferential points can only be allocated, if claimed.
34	The below products are not appearing on the bid: • Amoxicillin and Clavulanic Acid for suspension 250mg and 62,5mg/5ml; 100ml NSN number 180002786 and • Amoxicillin and Clavulanic Acid for suspension 125mg and 31,25mg NSN number 18000278.	The reason for these products not being advertised is that the Paediatric 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. The amoxicillin/clavulanic acid 14:1 ratio allows for an effective dosing with less adverse effects and is thus preferred.