

QUESTIONS FROM BIDDERS AND RESPONSES FROM NDOH FOR BID: NDOH 35-2023/2024

NO	QUESTION FROM BIDDERS	DATE	NDOH RESPONSE
1.	<ul style="list-style-type: none"> • The item HB meter is already on National RT2 Contract, why is it duplicated on NDOH35? • The specification for glucose meter requires that the glucose strips must be compatible with the dual HBa1C / Glucose meter. Does it mean only manufacturers that manufacturer dual meters are allowed to bid? Does it mean that if we offer a glucose meter that the strips can't work with a dual HBa1C / Glucose meter we will be disqualified? • As these items are new to go on national tender, did the tender department consult with industry or ask for RFI with regards to the specifications? • Some items are asking the following: "Accuracy: A minimum of 1 local correlation trials minimum) (Proof to be supplied for model of machine) Specificity and sensitivity should correlate with laboratory-based results. Bidder must be SAHPRA licensed for medical device" - must this be submitted with the bid closing? Since these tests are not positive or negative how does the lab work out the specificity and sensitivity without critical values being provided? This requirement is extremely vague and needs to be explained in detail. 	29 January 2024	<ul style="list-style-type: none"> • The department aims to group all POCT in the same tender basket into the future. The RT2 will expire soon in October 2024, only then will the award be effected for the item in question. • It is our preference as the department however, no bidder will be disqualified for offering strips that are not necessarily compatible to both dual and multi parameter items for singular items such HBa1C/ Glucometer, Ketone, and cholesterol meters. • Consultations happened with various provinces who are actively using the items in their various facilities. • The requirements are in line with the requirements of Policy on POCT, shortlisted bidders will be required to submit the correlation test results within 10 days of receiving the request from the department.

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	<p>Some items are asking the following: “Bidder must be SAHPRA licensed for medical device” this is contradicting the special conditions where you allow bidders to submit proof of SAHPRA application, this will also contradict the requirement of any local lab studies required by closing date as you cannot bring in materials for the study without already having a SAHPRA licence.</p>		<ul style="list-style-type: none"> Registration with SAHPRA is a legal requirement, however, to make provision for new entrants the proof of application i.e. acknowledgement letter will be considered. However, the final award will only be made upon producing the SAHPRA registration certificate as a medical device establishment.
2.	<p>As requested, please find our concerns. Many of these concerns are based on us supplying diagnostic equipment, to the government facilities, for over 10 years. This is to ensure that we as a supply, can offer you the most competent, competitive bid and that you as our client, have outlined effectively, what you require from ourselves.</p> <p>Firm prices for 3 years (Pg. 22) No prices subject to Rates of Exchange will be considered. Nothing in SCC re fluctuating of rate.</p> <p>To quote effectively on a 3-year tender you need to know all costs that would be involved, there is nothing in the tender specifications, to help you EG:</p> <ul style="list-style-type: none"> No point of delivery Which provinces are participating? Volume of items required, over the 3-year period and broken down into, year1, 2, 3, 	31 January 2024	<ul style="list-style-type: none"> There shall be non-firm pricing structure, bidders will have an option for ROE and other factors related to price adjustments over defined. Refer to the amended pricing schedule for a detailed information. There will be no defined quantities, defined delivery points as this will be a long term tender. Facilities, Provinces and National Department will buy as and when the need arises and budgets allow. kindly refer to “mandatory accessories and consumables” section of each specification item for guidance.

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	<ul style="list-style-type: none"> • Ratio of strips to meters • Line items need to be separate, at moment, buy 1 meter get pack of strips, this is not sustainable, as once they have the meter, don't need another one, with every order of strips but it requests pricing on ,1 meter and pack strips. <p>You can't work out a price on an item effectively, if you have no idea, how many may be required and no idea where it needs to be delivered.</p> <p>Although it states in specifications that standard consumables need to be bid on, there is no minimum order, how can we quote on the possibility of sending one box of strips or one battery, to a facility that could be many kilometres away. A minimum order number is required.</p> <p>SCC 8.3 Award to more than one bidder, same item but not same brand. How is that going to work? If Brand A is in a facility and they also award to Brand B, then the facility has to order, two different strips, as the brands are not generic and cannot be used in same meters. Unless they award per province, to different brands but same item. Very confusing.</p> <p>Also, some meters they have stated in specifications, they request Alkaline/rechargeable batteries, either or,</p>		<ul style="list-style-type: none"> • We have defined number of strips in terms of package size for both first time purchase with machine and individual purchasing of strips packages. • Prospective bidders must follow the pricing schedule for guidance. Prices quoted must be inclusive of all related costs. • Minimum order will depend on individual facility, district, province or national. • The strips have to be compatible (series) with each meter. • All will be acceptable for both alkaline and rechargeable batteries.

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	<p>but in other meters only rechargeable batteries e.g.: BP meter, Glucose Meter Standalone Glucose and HbA1C meters, strips need to be compatible with Dual Glucose/Hba1c meter.</p> <p>Standalone Cholesterol and Ketone meters, strips need to be compatible with multi meter. In briefing, this was raised as to whether you want both the dual meter with the standalone meters been compatible, as well as a standalone meter that would not be compatible with the dual meter. Clarity is needed. It appears that Bluetooth is required in all meters, this makes the meters more expensive, in our experience this facility is not utilised effectively by members of the public.</p> <p>We highly recommend a review be taken, as to the closing date of this tender, due to the uncertainty surrounding it. Please also note that the Chinese New Year, is taking place, so this effects the sourcing required products.</p>		<ul style="list-style-type: none"> • It is our preference as the department however, no bidder will be disqualified for offering strips that are not necessarily compatible to both dual and multi parameter items for singular items such HbA1C/ Glucometer, Ketone, and cholesterol meters. • It is a tender requirement therefore must be complied with. • Two weeks extension to closing date granted refer to the website of NDoH and OCPO for details.
3.	<p>In reading the specifications, it states that the dual HbA1C/Glucose meter, would be compatible with the stand-alone Glucose meter and HbA1C meter, their strips would operate in both meters. This due to Community workers, requesting this functionality. As these strips are more expensive, then normal stand</p>	01 February 2024	<ul style="list-style-type: none"> • It is our preference as the department however, no bidder will be disqualified for offering strips that are not necessarily compatible to both dual and multi parameter items for singular items such HbA1C/ Glucometer, Ketone, and cholesterol meters.

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	<p>alone, Glucose meter strips, it was assumed, that these meters would not be handed out to patients.</p> <p>In the briefing session, the question was raised, as to if the Department was only looking for these meters, as per specifications in tender documents or whether they would require a totally different, stand-alone Glucose Meter. The answer given, was that the Department would review the tender specifications and revert.</p> <p>As you may know, our company currently holds the National Glucose tender HP052021D1, which is expiring in June/July, we have distributed thousands of Glucose meters to facilities throughout South Africa, which have been handed out to patients. In order to effectively manage and continue to distribute meters and strips, we need to know if this tender NDoH-35 is the replacement of the current tender, we have or is there going to be a specific tender published for the replacement of HP052021D1? As you know, the order process for stock, is anywhere between 2-3 months and added to this, the delays in ports, it can be easily 4 months before we have stock, in our warehouses to distribute. With this in mind, we urgently need guidance from the Department, so we can maintain stock levels, to ensure continuity of supply to South Africa.</p>		<ul style="list-style-type: none"> • In the specifications document there is a standalone glucometer. Refer to our response on your 1st bullet point. • The glucometer in HP05 will be transferred under NDoH 35 going forward as was communicated during the HP05 briefing session.
4.	As requested, please see a list of questions that we seek clarity on:	01 February 2024	

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	<ul style="list-style-type: none"> • Downloadable/Installable Software on Smartphone and Computer Devices: Are there any specifications associated with the DMS and is it related to all the products under the tender scope or only some? If some, kindly highlight which ones. • Tender structure: Is there an estimated volume for in-hospital use, CHW, patients, etc. This information is important because the products will differ slightly based on where they will be utilized. • Annexure A: Section 4.5 under Glucose Meter: Strip to be compatible with dual meter: Can this specification be clarified and is it mandatory? • Section 4.1: Logistics Plan: Is there any commitment in terms of volumes for the duration of the contract? If we need to comply with the Key Functionality Requirements (logistics), we will need to know the expected volumes per province/district over the contract period. • Scoring based on specs: If a supplier cannot meet all the parameters on the product 		<ul style="list-style-type: none"> • It should be related to all products data as outlined under Dual GLuco_ HbA1c. • There will be no defined quantities, defined delivery points as this will be a long term tender. Facilities, Provinces, and National Department will buy as and when the need arises, and budgets allow. • It is our preference as the department however, no bidder will be disqualified for offering strips that are not necessarily compatible to both dual and multi parameter items for singular items such HbA1C/ Glucometer, Ketone, and cholesterol meters. • There will be no defined quantities, defined delivery points as this will be a long term tender. Facilities, Provinces, and National Department will buy as and when the need arises, and budgets allow. • Compliance to specifications will be reviewed by the bid evaluation committee as stated in the item specifications documents.

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	<p>specifications, will that affect their scoring for the product they are bidding with?</p> <ul style="list-style-type: none"> • Product demarcation: Do you require the product to be stamped “For Tender Use Only,” in order to ensure that it does not leak into the private market? • Can multiple bids be submitted by one bidder for additional products and services? • 2 Point allocation for Promotion of local enterprises: What is categorized as a SA owned enterprise? 		<ul style="list-style-type: none"> • Branding is a requirement on both item specifications and pricing schedule documents. • There is no prescribed format however the bidder must guard against uncompetitive bidding tendencies. • Companies that are registered and operate within the Republic of South Africa. This will be confirmed through the company registration information (CIPC).
5.	Is it compulsory that system must be handheld, battery operated or will a plug-in system that is portable and easy to carry suffice?	01 February 2024	It will be acceptable as long as it complies with the requirement of portability and easy to carry.
6.	<ul style="list-style-type: none"> • All the models ask for Bluetooth devices except for the Blood Pressure Monitor. Why not include a BPM that also has Bluetooth? • According to both Life Healthcare and Netcare the Bluetooth models in hospital use can affect some of the instruments especially in High and ICU care. Why is this a necessity to have Bluetooth models when a nurse is testing different patients. I can understand having a Bluetooth model if the meter is been given out 	02 February 2024	<ul style="list-style-type: none"> • It remains an option for bidders therefore not a disqualifying factor. • Answered above.

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	<p>to patients for self-testing as they can then send through their results to the hospital. A cholesterol, HB etc, does not require Bluetooth capabilities as these meters are not given out to patients.</p> <ul style="list-style-type: none"> • With regard to the HB meter required – A meter must be able to read Venous, Capillary and Arterial samples yet the Glucose meter which will be utilized much more especially in hospital use does not have this option. • Under Glucometer – It states that the strip has to be compatible with the dual meter which as was explained in the briefing that excludes every company that does not have a dual meter. • Rechargeable Batteries- As I am sure you have looked into this but in some of the specifications it has been noted Rechargeable / Alkaline batteries. The same has not been included in the specifications which gives most of the companies at a disadvantage as all new technology meters as requested uses the button battery. • Specifications require the latest technology meter – does this include the latest technology strip which is a strip that can utilize the GHD – FAD enzyme and not the GOD enzyme. 		<ul style="list-style-type: none"> • It is assumed that measurement methods such as capillary are standard in these devices. • It is our preference as the department however, no bidder will be disqualified for offering strips that are not necessarily compatible to both dual and multi parameter items for singular items such HBa1C/ Glucometer, Ketone, and cholesterol meters. • All will be acceptable for both alkaline and rechargeable batteries. • Latest technology as stated as long as the strips will be compatible with the meters.
7.	Regarding rechargeable batteries and what I have been able to find out is that all Glucometers that utilize	02 February 2024	<ul style="list-style-type: none"> • Comply with the specifications.

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	<p>meters with rechargeable batteries can only perform 100 -150 tests maximum.</p> <p>If the meter that a nurse/doctor uses especially in hospital use runs out of charge the Glucometer then has to be placed on charge which means in a hospital environment where a lot of testing is done the meter would be only capable of doing a maximum of 150 test before being placed on charge (Not been utilised for hours on end).</p>		<ul style="list-style-type: none"> • Comply with the specifications.
8.	<p>Amongst them the question of the compatibility of HBa1C & Glucose consumables to the respective Multimeters, just checking if this communication had already been published, we checked your website this week and couldn't find any new communication.</p> <p>One more question, If we submit the International correlation studies report instead of the local one for our products, would this be acceptable?</p>	06 February 2024	<ul style="list-style-type: none"> • It is our preference as the department however, no bidder will be disqualified for offering strips that are not necessarily compatible to both dual and multi parameter items for singular items such HBa1C/ Glucometer, Ketone, and cholesterol meters. • The local test is the one that is required in addition to the international correlation studies report.
9.	<p>You have now made provision, for ROE fluctuations to prices. On page 1 of the SBD3.2 document in regards ROE it states:</p> <p>IN CASES WHERE DIFFERENT DELIVERY POINTS INFLUENCE THE PRICING, A SEPARATE PRICING SCHEDULE MUST BE SUBMITTED FOR EACH DELIVERY POINT</p>	14 February 2024	<ul style="list-style-type: none"> • Unfortunately, at this point the department does not have the delivery points. Bidders are encouraged to work with the available information and ensure that their proposed prices are as inclusive as possible of all risk factors. Refer to the previous response as well.

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	<p>How do we submit a different pricing schedule, to delivery points, if you haven't given us the delivery points?</p> <p>On the third page of the same document B2, there are no dates as to when a ROE may be considered or what dates documentation, would need to be submitted to your offices, how do we know how many periods will be considered?</p> <p>In the specifications and in the questions submitted, it states "A minimum of 1 local correlation trials, Specificity and Sensitivity should correlate with laboratory-based results"</p> <p>What laboratory will be testing these units, as normally you need to ensure you have pre-paid to enable them to accept the units for testing?</p> <p>Also how does this apply to recently discovered products that may match the specifications of the tender that have never been used, in the South African market?</p> <p>You refer to the policy of POCT, please could you send us a link to this policy or to what institute, has published it.</p>		<ul style="list-style-type: none"> • The department is busy considering this question and the response will be published tomorrow the latest. • Bidders may arrange with their own SANAS accredited laboratories or as the BEC may guide where arrangements may be made with NHLS for which bidders will still be liable for payments. • It still has to comply with regulatory and policies requirements of the country. • The POCT will be uploaded where the bid document was published.

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	<p>As to the separate line items for the meter /strips and the continuation of purchasing strips for meters going forward, you refer to the package as a starter pack and have stated “We have defined number of strips in terms of package size for both first time purchase with machine” So once a facility has purchased the package for the first time, they will then only place orders for strips?</p> <p>In your Q&A reply, it is stated “Prices quoted must be inclusive of all related costs “</p> <p>How do we include transportation, which is a definitive cost, if you do not supply defined delivery points?</p> <p>I reiterate my point, made in the last correspondence to yourselves, by not having all the data needed to quote, on such a large tender, which is of vital importance, to the maintenance of health in South Africa, you are setting yourselves and potential suppliers up for failure. Once it does not become economically viable, to supply, due to hidden costs, the supplier will simply stop, which results in a failure of the whole process.</p>		<ul style="list-style-type: none"> • Refer to our previous response on this question. • Unfortunately, at this point the department does not have the delivery points. Bidders are encouraged to work with the available information and ensure that their proposed prices are as inclusive as possible of all risk factors.
10.	<p>To whom it may concern.</p> <p>I have recently returned from Dubai, where they host the Arab Health/Medlab medical shows. These are one of the biggest medical shows historically, where</p>		<ul style="list-style-type: none"> • The department does not get involved in the private sector contract agreements therefore the exclusivity or sole provider or multiple provider agreements should be a private matter between OEM and local distributors.

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	<p>suppliers from all over the world congregate, to display their products.</p> <p>Having attended the briefing session for the NDOH 35 - 2023/2024 tender, I was excited to discover products that may fit the specifications, laid out in the tender. It came as a bit of a disappointment, to discover that the exact specifications, as stated in the tender documentation, matched a meter that was being supplied by a Chinese Manufacturer, at the show and that they had already signed an exclusivity of supply, to South Africa, in the year of 2023, with a South African company, namely Tara Healthcare.</p> <p>Mr Yan Liang from Nanjing Eaglenos knew everything about the tender and agreed that his meter matched the specifications exactly. He acknowledges that they were the only suppliers of that particular Multi Meter, with those parameters.</p> <p>Prior to traveling to Dubai, I sent a request to all our current suppliers, to source this Multi Meter matching the tender specifications, not one supplier could offer me that product. We have been supplying into the South African Market, with diagnostic consumables, for 15 years and have access to numerous suppliers, world-wide.</p> <p>Please advise how we can submit a competitive bid if the specifications, are brand specific?</p>		<ul style="list-style-type: none"> As such the department does not have any such agreements with any supplier/s or OEMs.

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	<p>Please follow this link, to find the company involved and the specified Multi Meter.</p> <p>https://www.eaglenos.com/en/products-2/</p>		