health
Department:
Health
REPUBLIC OF SOUTH AFRICA

QUESTIONS AND ANSWERS – BRIEFING SESSION 30 JUNE 2023 BIDS HP04-2024ONC, HP05-2024DI AND HP06-2024SSP

No.	Question	Answer
1	Gooday if the cession of the MRC is submitted and SAHPRA has not yet reviewed how do we handle this?	The Department of Health will only consider items that have been reviewed and approved by SAHPRA at the time of bid closure.
2	Is the letters of cession and proof of submission to SAHPRA valid?	See answer to question 1.
3	We have applied for a variation on an existing MRC. However, the outcome of the variation has not been finalised. Can we submit a copy of the variation application as part of the bid?	The Department only accepts offers that has been reviewed and approved by SAHPRA at the time of bid closure even if companies applied for variation in the already approved product. A certified copy of the MRC and the variation summary must be included with the bid to ensure the bid is responsive. By submitting a variation application, the Department will only note that the bidder has applied for a variation and that approval is still pending from SAHPRA. The offer will be deemed non-responsive.
4	If variations have been submitted to SAHPRA and changes to PI but not approved must the proof of submission be submitted.	See answer to question 3.
5	Can we have a copy of slides and presentation?	The presentation is available on the NDOH website for download by bidders.
6	Cold Chain sample submission - do we have to maintain the cold chain when submitting the samples?	Yes, cold chain products need to be maintained at all times to ensure the stability and integrity of the product.

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7	Supplier Due Diligence: This may include site visits to assess whether: the bidder has two (2) months buffer stock on hand. Will this be conducted prior to award? What about companies that do not have stock as YET? vs the 75 initial lead time	Due Diligence can be conducted prior to the award or any time during the contract period. The Department may assess if the contracted supplier has two (2) months buffers stock on hand after the contract has been awarded.
8	With reference to HP05-2023DI items 8 & 9: MRI Contrast Media can be classified into to two types: 1. Linear 2. Macrocyclic Each type of molecule noted above contains Gadolinium. I quote form the European Medicines Agency website: “On 20 July 2017, the European Medicines Agency (EMA) concluded its review of gadolinium contrast agents, confirming recommendations to restrict the use of some linear gadolinium agents used in MRI body scans and to suspend the authorisations of others. There is currently no evidence that gadolinium deposition in the brain has caused any harm to patients; however, EMA has recommended restrictions and suspensions for some intravenous linear agents in order to prevent any risks that could potentially be associated with gadolinium brain deposition. Another class of gadolinium agents known as macrocyclic agents (gadobutrol, gadoteric acid and gadoteridol) are more stable and have a lower propensity to release gadolinium than linear agents. These products can continue to be used in their current indications but in the lowest doses that enhance images sufficiently	The query has been referred to the Essential drugs Programme (EDP) for review by the Essential Medicines List Committee (NEMLC). Please forward further inquiries to SAEDP@health.gov.za.

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	and only when unenhanced body scans are not suitable." The above information is quote from the EMA website and can be reviewed on the Following link: https://www.ema.europa.eu/en/medicines/human/referrals/gadolinium-containing-contrast-agents Thus, the EMA have suspended the Gadopentic acid (Tender Item Number 9), they have also stated that the use of Gadobenic acid (Tender item Number 8) be restricted to liver scans. The use of Macrocyclic type MRI contrast has been promoted and there are currently companies in South Africa that can supply an alternative and safer molecular structure. The then Department of Health (SAPHRA) were informed of the risk in writing in 2018 as attached and they requested all MRI Contrast companies to respond accordingly with respect to their own safety profiles and data related to the molecules being used. With respect to the information noted above, we as Guerbet are still surprised to see this product being requested even though the EMA has not recommended the use thereof and that the EML Team and SAPHRA have been informed of these risks associated with the requested tendered MRI Contrast Media products. We would like to request that Macrocyclic MRI Contrast Media Products be included into this tender due the safety profile of the molecule for the benefit of the patients from Neonates to the elderly with no confirmed cases of NSF and no brain deposition to date, which is more	

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	widely associated with Linear MRI Contrast agents.	
9	With reference to HP05-2023DI Items 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21: The tender should include all the Low Osmolar Contrast Media manufacturers to tender accordingly. The current Tender technical specifications exclude XRAY Contrast Media products based on the specific chemical structure, and this is seen as an exclusion. The contrast tender should be open to all contrast media suppliers in South Africa by stating the concentration in mg and the packaged volume required. Example: • Xray Contrast Media required with a concentration of 300 to 320mg, 100ml Vial If the suggested methodology is utilised, it will open the tender to all suppliers if the bid technical specifications are within reach to all contrast media suppliers.	The items that are advertised should meet the following criteria: • Is approved by NEMLC, • It is listed on the Essential Medicine List (EML), and • It is used by the Participating Authorities (PA) Note: The Participating Authority indicates the quantities that are required. Even if the item is on EML, if there is no demand from the PA the item will not be advertise on tender.
10	When deciding on bid price, as bidders we naturally do consider the SEP on the product line and generally ensure that the bid price is not higher than the SEP. Since SEP regulation has been in use now for around 2 decades to-date, over the years and more recently, SEPA has been granting SEP increases of not more than 5% on average, a fair number of items have begun to show trend of production costs increasing at a rate higher than the price increase, and this is common in difficult to make lines such as oncolytic.	AMD has taken note of the concerns raised and will share it with the relevant stakeholders.

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	The effect of this can be seen in tender prices that at times comes close to SEP itself. Now at these price level if bid price is close to SEP price point, and the RoE shift adverse, resulting in a need to adjust the price high, the quantum of the shift will likely move above the prevailing SEP level. Should an application be made for the item to have its SEP adjusted, the only available mechanism is the use of Regulation 9, which takes up to 6 months (180 days), and results of the application may or may not be favorable for the supplier. If a product line experiences the above scenario in the private sector market, a line can be discontinued if the costs exceed the SEP and the regulation 9 Is not granted, or by virtue of the 180 days waiting period, often item will be perceived to hold cost risk for the company. However, should the same line have series of other packs or dosages (strengths), and those strengths are still SEP viable to continue to sell, also if such dosage forms make up higher volume than the dosage form with costs risk, common decision is to keep the full range as there is cross subsidization effect on full brand level. State often drives higher volume, any product costs risk relative to the prevailing SEP level, may push bidders to not bid, this hold ticket to worsen the current challenges we have of high non award SKU count, which is an increasing trend recently. Suggestion Allow threshold above SEP for certain categories of products, e.g., Oncolytic, Biologics and other difficult to make items. 10 - 15%. Threshold to be applied to RoE discretional decision, expectation to present proof to the effect is logical.	

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11	For Package inserts and Medicine registration certificates -can we certify only the first page?	The PI does not have to be certified at all as is indicated in the index of the Special Requirements and Conditions of Contract. All pages of the MRC must be certified as a true copy.
12	What about an approval with recommendation? SAHPRA can approve a variation with a minor recommendation like submit an additional document that has no Quality or efficacy impact on the Final product.	When submitting a bid all SAHPRA approvals must be included. Each item is assessed on its own merit and should further clarity be required, AMD will contact the bidder.
13	What is the estimated date to finalise tender HP04-2024ONC.	The bid validity of HP04-2024ONC expires in February 2024. The Department of Health always strives to award contracts before the validity expiry date, but should it not be the case all bidders will informed accordingly.
14	Fresenius Kabi is currently busy with implementing product name changes – these are not significantly different from current name but does require that the company name, is moved to the end of the brand name. This will occur in stages over the next 6-8 months. For the HP06-2024 tender, is FRESENIUS KABI required to submit the new Package insert and new Medicine registration certificate, although the actual selling pack name change and the DOH database name change has not yet been updated?	When submitting a bid all SAHPRA approvals must be included. Each item is assessed on its own merit and should further clarity be required, AMD will contact the bidder.
15	Regarding submission of variations to SAHPRA? Please advise if you need a copy of the clinical and technical information submitted in the application, or just the letter for proof of submission/application?	There is no need to submit the Clinical and technical information submitted in the application. Please note the answer to question 3.

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16	1. Removal of Items 4 & 5, Glucose meter & Strips – Do you have the new tender number this will be published under? 2. As Item 27 – Urine Analysis strips, is this still included under the above tender number as this also falls under the Diagnostic category or will this item be under a new tender number as well.	1. We have been informed that the Department will initiate a Point of Care Testing (POCT) tender that will include these products. For any further inquiries please contact the Health Technology Directorate, Mr S Bakhane (details below). 2. Yes item 27 remains on HP05-2024DI.
17	Can you please introduce me to the department responsible for the tender for the Glucose meters and strips removed from	Mr Sam Bakhane Tel: 012 395 9209 E-mail: setlhare.bakhane@health.gov.za Directorate: Health Technology
18	We note that some items are now being awarded as a series why is the case on HP06-2024 items 106 and 107 as well as 126 and 127	An erratum has been published to correct the class and Series on HP06-2024SVP. Please download the erratum bid pack on the NDOH website and use this bid pack to submit your bid.
19	HP06-2023SVP – Surfactant group2 According to the tender specifications, **pg 67 of 88**, Class 1b the Surfactant-group2 (as highlighted in yellow) under item specification the Natural Phospholipids (Poractant alpha) molecule has been included twice vs the Class 1a where both the Poractant and Beractant have been included. Could you please advise on this description i.e. that in class 1b only the Poractant will be considered and not the Beractant. Kindly refer to the next pg 68 and the Final Bid Response excel sheet which both indicate the inclusion of the Beractant in class 1a and class 1b for your reference. Secondly as these are competing therapeutic classes, the units called for also differ across the molecules. Please see pg 86 item 106 & 107 vs pg 87 item 126 and 127. Please confirm if the discrepancy in units advertised is correct.	Please refer to the answer to question 18.

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20	In the briefing session for HP06 please would you clarify the difference between locally manufactured product vs South African Owned enterprises as it relates to claiming the 2 points. The products are 100% locally manufactured (API imported only). The company is 51% South African Owned. Is this company entitled to claim 2 points or only 1 point under the RDP goal?	Local manufacturing in relation to an item refers to product formulation and conversion processes that use materials and components to manufacture medicines (including importation of raw material of active pharmaceutical ingredients (API) and of excipients for production of finished products) in the Republic of South Africa. This is not an RDP goal, whereas promotion of South African owned enterprises is. Therefore the % equity ownership held by South Africans in the enterprise will be used to calculate points. If the enterprise is 51% owned by South Africans, the points claimable will be 1.02.

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