HEALTH
REPUBLIC OF SOUTH AFRICA

ONLINE BRIEFING SESSION – 1 July 2022
QUESTIONS AND ANSWERS

No	Question	Answer
HP04-2022ONC/01, HP06-2021SVP/02, HP07-2023DAI, HP08-2023SSP, HP09-2023SD		
1.	If a product is in process of transfer of applicancy can new applicant place bid with letter of transfer from previous applicant.	Paragraph 4.2 of the SRCC states that the bidder must be the listed as the applicant of the product. For a bidder to be listed as the applicant the process ought to have been considered at SAHPRA. As NDOH cannot pre-empt SAHPRA's decision, only items that have been finalised by them are considered.
2	If items are considered a series but we dont have all the strength, can we bid?	You may place a bid but may not be successful depending on the dynamics of the bids received. In most instances all strengths in a series are required for dose titration or incremental dosing. You may place a bid and the Evaluation Committee will consider the need of the Department when making a recommendation for award.
3	Please advise more or less when the tender will be awarded so that we know how long we have to deliver the first order - for tender bidHP09-2023SD.	The bid validity period is 180 days after bid closure. It is always the intention of the NDOH to award before bid validity expires. However, we will strive to award at least two months before the current contract expires. Regretfully, an exact date and time of award cannot be indicated.
4	Will there be a possibility of a split where an item is not in a class but there are other alternatives?	Paragraph 20.1 of the SRCC states that the NDoH reserves the right to issue a split award taking into consideration the following, 1. API Source and Manufacturing site 2. Capacity to meet demand 3. Estimates volumes to be supplied 4. Risk to public health if the item is not available 5. Past compliance of the bidder with contractual compliance Furthermore, the formulas for split awards are also explained in the SRCC.

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5	Since the first bid advertised for HP09-2023SD was cancelled a lot of work was already done. Can we still use the Authorization letters received from manufacturers already obtained on the new bid advertisement	It will be wise to ask your third-party manufacturers to issue another letter which is aligned with the new tender advertisement dates.
6	If a tendering company currently has representative samples of 30s and 60s instead of the stipulated 28s and 56s, can we submit those samples? The tendering company currently in process of Transfer of applicancy.	Kindly refer to the answer regarding Question 1 above, i.e. transfer of applicancy Paragraph 4.3 of the SRCC states inter alia that: Bidder's must submit at least one original pack of each offer and that all samples must be a true representation of the product that will be supplied. It is advisable to comply with these requirements. Kindly note that should you place a bid for example, a product with a pack size of 30's and the specification requires a pack size of 28's you are allowed to do so as is prescribed in paragraph 20 of the SRCC.
7	Can we replace the awarded brand during the tender period with the same molecule e.g. replace originator with a clone?	It's not feasible to replace the awarded brand during the tender period with the same molecule. Should you have any intentions doing so, please ask approval from the NDOH as is prescribed by the SRCC.
8	We were pointed toward this meeting in order to understand how we could go about applying for a tender on a unique product for neurosurgery. Would it be possible to help with this?	By attending this briefing Session it hopefully gave you some background on the Pharmaceutical Tenders administrated by AMD. Neurosurgery items seems to be medical related items that is managed by National Treasury. Since this is a medical device kindly contact National Treasury Transversal Contracting Unit:

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9	Is it essential that each bid item have an SEP?	It is not compulsory for an item which is intended for use in the public sector to have an SEP.
10	The SRCC does not indicate Local Packaging any more under Local Preference, why has it been removed or was this an omission, is Local Packaging not being considered anymore?	Paragraph 6 of the SRCC states that a locally produced product will be limited 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. The criteria for assessing locally produced product is aligned with the definition of locally produced product.
11	Our certification has been done already on our documents for the cancelled tender will this be accepted as it is not older than 3 months, furthermore we received our PBD5 and PBD8 via courier from India for previous tender it will be difficult to obtain new ones before the closing of the tender will they be acceptable for the new tender.	Certification should be in order, however the PBD5 and PBD8 should be completed again to be in line with the new bid pack advertisement dates.
12	Currently have items being registered with SAPHRA applicancy change and will submit the Tech Transfer application – the question is what type of Sample should we submit the previous applicant or our own.	Please refer to answers relating to question 1 and 6 above.
13	Kindly request assistance regarding submission of the currently published tenders. We are in the application process for our SAPHRA manufacturing license as per attached letter. The	Paragraph 4.1 of the SRCC states that the bidder offering a product must be the holder of the licence to manufacturer or import medicines issued in terms

	molecules that we sell are in Abex Pharmaceutical name and we are the marketer for now as we anticipate the approval of our SAPHRA manufacturing license. After we receive our SAPHRA manufacturing license, we will transferred all the molecule applicants on the Medicine Registration Certificate to Encha Health. We would like to know if we can participate on the published tenders as Encha Health, because Abex is not BBBEE compliance.	of section 22C (1) (b) of the Medicine and Related Substances Act 1965. The Bidder must also be indicated as the applicant on the Medicine Registration Certificate. At the time of bid closure all bidders must be compliant to this legal mandatory requirements. If not the bid will be deemed non responsive. Preference Points for B-BBEE is only allocated to the Bidder if it complies to all the requirements as stated in paragraph 5.2 of the SRCC.

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