health
Department:
Health
REPUBLIC OF SOUTH AFRICA

QUESTIONS AND ANSWERS – BRIEFING SESSION 5 JUNE 2024
BIDS HP06-2027SVP

No.	Question	Answer
1	What is the process for applying for price adjustments due to both local and international/foreign cost increases?	Price adjustments during the contract period will be considered in accordance with the contract provisions and approved price adjustment methodology applicable to the contract. Requests must be supported by the required documentary evidence stipulated in the contract. Suppliers who believe that the current methodology no longer adequately addresses industry cost pressures are encouraged to engage through their recognised Stakeholder Forum Representatives.
2	How is local manufacturing considered in the evaluation process?	Local manufacturing is considered through the requirements and evaluation provisions contained in the SRCC and associated bid documents. Bidders claiming local manufacturing, local production activities or technology transfer arrangements must submit the supporting evidence required by the SRCC.
3	Where can the latest version of bid documents be accessed?	The latest version of the bid documents is available on the National Department of Health website and the eTender Portal.
4	What is the procedure for reporting incorrect or incomplete bid documents?	Any incorrect or incomplete bid documents should be reported via email to Tenders@Health.gov.za.
5	Where can definitions and guidelines for the required documentation be found?	Definitions and guidelines for required documentation can be found in the SRCC. Refer to the table of contents for the relevant sections.
6	Where can definitions and guidance on the completion of required documentation be accessed?	Definitions and guidance on completing required documentation are contained in the SRCC. Additional clarification may be obtained through the published briefing session questions and answers.
7	How can further clarification be obtained if document completion requirements remain unclear?	Further clarification may be obtained by contacting Tenders@Health.gov.za.
8	If a submission deadline falls on a weekend, when should performance and delivery reports be submitted?	Where a submission deadline falls on a weekend, reports should be submitted before the weekend.
9	How should challenges related to participating authorities' purchase orders and payment processes be managed?	Suppliers should engage directly with the relevant participating authority. Where all available resolution mechanisms have been exhausted, the matter may be escalated to the Contract Management Unit (CMU).
10	Under what circumstances is a package insert not required?	Package inserts are generally not required for medical devices, equipment or other non-medicinal products. Alternative documentation such as Instructions for Use (IFU) or product information should be submitted where applicable.
11	What is meant by the term "Technology Transfer" in this context?	Technology transfer refers to the systematic transfer of a manufacturing process, associated documentation, expertise and quality systems from one entity or site to another, including arrangements supporting local pharmaceutical manufacturing.
12	When is it acceptable not to submit samples?	Physical samples are generally not required for Schedule 6 medicines. However, bidders must submit the primary packaging artwork and approved package insert or professional information.

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13	How should samples of psychotropic medications that are not yet marketed locally be handled?	Where a SAHPRA-registered product is not yet marketed locally, a mock sample may be submitted. The mock sample must be a true representation of the product to be supplied if awarded.
14	Where can the Essential Medicines List (EML) and non-EML items be accessed?	The EML and related information are available through the National Department of Health Essential Drugs Programme (EDP) portal.
15	Is a company resolution required with the bid submission?	No. The Department no longer requires submission of a seperate company Board Resolution as part of the bid response. However, bidders must ensure that the person/persons signing the bid is duly authorised to do so on behalf of the bidding entity. All director`s signatures should be presented in Table 1 of the PBD3 / PBD3.1 document.
16	Wording on the SBD1 bid document refers to a resolution, is it therefore not a requirement to include the separate Board Resolution?	No, only the PBD3 will be required. The wording on SBD1 does not create a mandatory requirement for a Board Resolution. It merely reference an example "e.g. company resolution"
17	Does the Package Information Leaflet (PI) need to be certified?	Original SAHPRA-approved Package Information Leaflets submitted in their original leaflet format do not require certification. Where a bidder elects to submit an A4 reproduction of the SAHPRA-approved PI, the A4 version must be certified as a true copy of the approved PI.
18	Are GMP certificates required as part of the bid submission?	No. GMP certificates are not required as part of the bid submission. Bidders must submit a valid manufacturing licence where applicable and complete PBD5, which includes confirmation that the bidder accepts responsibility for GMP compliance.
19	Why was Pethidine not included in HP06-2027SVP?	Pethidine was not included in HP06-2027SVP because it is classified as a non-EML item and therefore does not form part of this contract.