



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

QUESTIONS AND ANSWERS: HP16-2027EPI
NON-COMPULSORY BRIEFING SESSION 5 SEPTEMBER 2025

No.	Question	Answer
1.	Clarity sought on the joint venture/consortium requirement. The RFP does not make provision for a situation where the Bidder is not the applicant, and the two entities are companies in the same group. There would not be a consortium/JV agreement but a commercial arrangement (licensing arrangement) between the two entities. Is this sufficient?	<p>Yes, a formal commercial agreement will be acceptable.</p> <p>The key requirement is that any such agreement must clearly define the relationship and responsibilities between the entities and remain valid from bid closure through to the end of the contract period.</p>
2.	<p>With regards to the CIPC documents required:</p> <p>It is my understanding that older business entities only have a CM1. Cor14.3 is the certificate of registration issued by CIPC for newer companies. Is it in order to submit the CM1?</p>	<p>Yes, it is for older entities, the CM1 certificate of incorporation serves as valid proof of registration, just as the CoR14.3 does for newer companies.</p> <p>Both documents meet the SRCC requirement to provide CIPC registration evidence.</p> <p>However, CM1 or CoR14.3 might not reflect current directors, therefore, any director changes and the current list of directors must be confirmed through CoR39 filings and the latest CIPC disclosure certificate.</p>
3.	Is the A4 printed version of the Package Insert sufficient?	Yes, A4 package insert is sufficient.
4.	<p>PBD3 – in the event of a partnership / consortium</p> <p>Should each party in the partnership complete an individual PBD3 forms</p>	<p>In this context, it is essential that all directors are clearly identifiable.</p> <p>The purpose of the PBD 3 form is to confirm who has been duly authorised to represent the bidding</p>

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	<p>or is it requirement of the tender that one PBD3 form to be completed listing the directors of both parties in the partnership?</p>	<p>entity in signing and submitting the bid documentation.</p> <p>Where the bid is submitted by a partnership, consortium, or joint venture, all participating entities and their respective directors must be listed. The accompanying resolution must explicitly designate the individual(s) authorised to act on behalf of the collective entity for the purposes of finalising and submitting the bid.</p>
5.	<p>Local Manufacture: PBD5 vs SAHPRA GMP</p>	<p>Both documents are required for local manufacturers:</p> <ul style="list-style-type: none"> • PBD5: Declaration of compliance with GMP, • SAHPRA GMP certificate: Approved GMP certificate from SAHPRA.
6.	<p>Reference Price Calculation</p>	<p>Benchmark reference prices are determined using a combination of:</p> <ul style="list-style-type: none"> • Local procurement data; • International pricing benchmarks, such as PAHO vaccine prices; and • Market intelligence. <p>For Items 3, 4, and 5 (rotavirus vaccines, containing at a minimum per dose: monovalent or multivalent live-attenuated human and/or bovine rotavirus strains in a fully liquid formulation), a weighted average reference price per dose was applied to account for all available presentations. Where PAHO pricing served as the reference, adjustments were made to incorporate VAT and domestic logistics costs in South Africa, thereby establishing a realistic benchmark for evaluation purposes.</p>
7.	<p>Certification of the MRC and Variation Summary</p>	<p>Documents may be submitted as copies of the original documents, provided that each individual copy bears its own original certification.</p>

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8.	Clarification on Required % Shareholding and Point Allocation	<p>The 90/10 preference point system applies: 90 points for price, and 10 points for specific goals (HDI and RDP as per SBD6.1).</p> <p>1. No minimum % requirement</p> <p>There is no prescribed minimum percentage of shareholding required for women, persons with disabilities, or other HDIs.</p> <p>Points are awarded strictly in proportion to the actual shareholding held by qualifying individuals, if ownership is proven with valid supporting documentation (e.g., share certificates, share register, CIPC)</p> <p>Category-specific allocation</p> <p>HDIs (Historically Disadvantaged Individuals): Points are awarded in direct proportion to the percentage shareholding of HDIs in the bidding enterprise. Gender / Female / Women: Points are awarded in proportion to the percentage of shareholding held by women.</p> <p>Persons with Disabilities: Points are awarded in proportion to the percentage of shareholding held by people with disabilities.</p> <p>RDP Goal (South African Ownership): Points are awarded based on the percentage shareholding held by South African citizens in the bidding enterprise.</p> <p>The formula</p> <p>The allocation follows a simple ratio calculation:</p>

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		<p>Points Allocated = (% Ownership) × (Maximum Points Available for Category)</p> <p>Examples:</p> <ul style="list-style-type: none"> • If HDIs hold 50% shareholding, then $50\% \times 4 = 2$ points (out of 4 HDI points). • If women hold 10% shareholding, then $10\% \times 2 = 0.2$ points (out of 2 gender points). • If persons with disabilities hold 25% shareholding, then $25\% \times 2 = 0.5$ points (out of 2 disability points). • If South Africans (whether HDI or not) hold 100% shareholding, then $100\% \times 2 = 2$ points (out of 2 RDP points). <p>Cumulative application</p> <p>HDI shareholding percentages should also be reflected in the RDP (South African ownership) section. In cases where ownership is partly HDI and partly other South African citizens, the RDP % = HDI % + non-HDI South African % supported by share certificates, share register, CIPC.</p>
9.	Documentation Required for Trusts and for showing management of Trust	<p>Where equity is held through a Trust, the following are required:</p> <ul style="list-style-type: none"> • Certified Trust Deed, listing individual trustees and individual beneficiaries and their roles, • Share certificate confirming ownership held by the Trust in the bidding enterprise. • Certified copies of ID documents of qualifying individuals. <p>Application to Trusts</p>

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		<p>In terms of evidence that beneficiaries and/or trustees are HDIs and actively involved in management - the content of the Trust Deed is used. Points as claimed will be evaluated and allocated where the Trust Deed clearly stipulates the role of trustees in the management of the Trust. A trustee, by definition, is entrusted with management of the Trust and therefore qualifies as being part of management. Where the same individuals are both trustees and beneficiaries, and their names are expressly stated in the Trust Deed, they will qualify for the allocation of preference points in line with the applicable ownership percentage of the Trust held in the bidding enterprise.</p> <p>Beneficiaries who merely receive benefits, but are not trustees, do not participate in management and therefore do not qualify, furthermore, the number of Trustees is considered. The % of all Trustees listed in the Trust Deed - that are also beneficiaries, will determine the % used for calculation of points in each SBD6.1 category, and will be limited to the % ownership held by the Trust in the bidding enterprise.</p>
10.	Procurement Class and Evaluation of Cost per Fully Vaccinated Child	<ul style="list-style-type: none"> • A procurement class refers to a grouping of vaccines containing the same active ingredient but offered in different presentations, pack sizes, or dosage forms. Within each procurement class, only one item will be awarded to maintain standardisation in the Expanded Programme Immunisation (EPI). • For evaluation purposes, the Department will consider the total cost per fully immunised child in line with the EPI schedule. For

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		<p>example, where three doses of a rotavirus vaccine are required to complete the schedule, the cost of three doses will be compared against the cost of two doses in cases where only two doses are required to achieve full immunisation.</p> <ul style="list-style-type: none"> • As a weighted average reference price per dose has been applied in the calculation, the cost of wastage will not be factored into the evaluation.
11.	Item 10 – Acellular Pertussis Requirement	<p>Item 10 specifies acellular pertussis (aP) as a mandatory component. A product registered with whole-cell pertussis does not meet the bid specification and will therefore be deemed non-compliant.</p> <p>Since the whole-cell pertussis formulation differs from the product recommended in the Standard Treatment Guidelines (STGs), the National Advisory Group on Immunisation (NAGI) will be required to review the available clinical data to determine whether such a product would be suitable for use in the South African context. Accordingly, deviations to whole-cell formulations will not be considered, unless and until a positive recommendation from NAGI is available.</p> <p>The Department further confirms that it cannot provide assurances of expedited SAHPRA approval; the registration process remains the sole responsibility of the applicant under the Medicines and Related Substances Act.</p>

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12.	Split/Multiple Awards (SCC 20.3)	<p>Historically, and in the case of HP16-2027EPI, single awards are made on EPI contracts to ensure efficient programme implementation. This approach facilitates coordinated planning, accurate cold chain management, standardised healthcare worker training, effective demand creation, and uniformity in vaccine presentation.</p> <p>While Section 20.3 of the SRCC allows for split awards, this option will only be considered where no single supplier has the capacity or is able to meet the required tender volumes.</p>

For any additional queries, bidders are encouraged to contact: tenders@health.gov.za