GUIDANCE ON REGULATORY REQUIREMENTS FOR COMPLEMENTARY MEDICINES OFFERED IN NATIONAL PHARMACEUTICAL TENDERS

The National Department of Health (NDoH) has obtained clarification from the South African Health Products Regulatory Authority (SAHPRA) regarding the licensing and product-listing requirements applicable to complementary medicines offered in national pharmaceutical procurement processes.

The following information is provided to assist all current and prospective bidders in understanding the regulatory documentation required to enable the Department to validate complementary medicines during bid evaluation.

SECTION 22C LICENSING REQUIREMENTS

SAHPRA has confirmed that where an applicant holds a valid Category A licence to manufacture, import or export medicines, a separate licence for complementary medicines (Category D) is not issued. Rather, the Category A licence holder must have the relevant complementary medicines appropriately approved and included on the applicable product list through the DA02 amendment process.

Accordingly, the absence of a separate Category D licence does not render a bidder non-compliant where the applicable Category A licence is held and the complementary medicines offered are appropriately reflected on the SAHPRA-approved DA02 Product List.

For purposes of bid evaluation, the applicable licence must therefore be considered together with the corresponding DA02 Product List. The regulatory documentation submitted must enable the Department to verify that each specific complementary medicine offered is appropriately authorised and reflected on the applicable SAHPRA-approved DA02 Product List.

Bidders should therefore ensure that the licence and all applicable annexures and product lists submitted with the bid collectively demonstrate the regulatory status of the products offered.

THIRD-PARTY MANUFACTURING ARRANGEMENTS

The Department recognises that complementary medicines may be manufactured on behalf of an applicant or bidder by an appropriately licensed and authorised third-party contract manufacturer.

The use of a third-party manufacturer does not, however, remove the requirement to establish the regulatory status of each specific product offered.

Where third-party manufacturing arrangements apply, the relevant licences, DA02 Product List, Bid Response Document, PBD 1.1 and PBD 1.2, together with any other required supporting documentation, must collectively establish a clear and verifiable link between the bidder/applicant, the authorised manufacturer and each product offered.

A third-party manufacturer's licence confirms that manufacturer's authority to undertake the relevant manufacturing activities but does not, on its own, establish that a particular complementary medicine offered by a bidder is approved and reflected on the applicable SAHPRA-approved DA02 Product List.

Bidders should therefore ensure that the complete regulatory and supporting documentation submitted with the bid enables the Department to establish this relationship without relying on assumptions or information that cannot be objectively verified from the bid submission.

PRODUCT NAMES ON THE DA02 PRODUCT LIST

SAHPRA has confirmed that only complementary medicines appearing on the approved DA02 Product List are regarded by SAHPRA as approved products under that list.

Where the name of a product offered in a bid or marketed by an applicant differs from the product name appearing on the applicable DA02 Product List, the Department cannot assume that the difference is merely administrative, stylistic or non-material.

SAHPRA has advised that differences may, for example, relate to a formulation change, intended-use change or product-name change. Such changes must be submitted to SAHPRA for review and approval.

Accordingly, the Department cannot independently determine that two differently named products constitute the same SAHPRA-approved product. The product name reflected in the bid documentation must therefore correspond with the product approved and reflected on the applicable DA02 Product List, unless appropriate SAHPRA-approved documentation is submitted confirming the relevant change or correspondence.

Bidders are therefore advised to verify, prior to bid submission, that the product names entered in the Bid Response Document correspond with the names appearing on the applicable SAHPRA-approved DA02 Product List.

PRODUCTS NOT REFLECTED ON THE DA02 PRODUCT LIST

SAHPRA has confirmed that products not included on the approved DA02 Product List cannot be regarded by SAHPRA as approved products under that list.

Accordingly, a complementary medicine offered in a bid that cannot be identified and validated against the applicable SAHPRA-approved DA02 Product List cannot be accepted as meeting the applicable product-listing requirement.

The submission of a valid licence, including a licence held by a third-party manufacturer, does not on its own establish the regulatory approval of a specific product where that product cannot be validated against the applicable DA02 Product List.

DA02 AMENDMENT APPLICATIONS

Where an application has been submitted to SAHPRA to amend a DA02 Product List, bidders should distinguish between submission of an amendment application and SAHPRA approval of that amendment.

SAHPRA has confirmed that it can only confirm products, including product names, as approved where these are reflected on the approved DA02 Product List. Accordingly, the submission of a DA02 amendment application does not establish that the proposed product inclusion or change has been approved by SAHPRA.

For procurement purposes, bidders must therefore submit the applicable SAHPRA-approved regulatory documentation required by the relevant bid conditions to enable the Department to validate the product offered.

GUIDANCE TO BIDDERS

Bidders offering complementary medicines are advised to carefully review their regulatory documentation before submitting a bid and ensure that:

- the appropriate valid Section 22C licence and relevant annexures are submitted as required by the applicable bid conditions;
- where a Category A licence applies, the complementary medicines offered are appropriately reflected on the applicable SAHPRA-approved DA02 Product List;
- each product offered in the Bid Response Document can be clearly and objectively matched to the corresponding product on the DA02 Product List;
- product names used in the bid correspond with the SAHPRA-approved product names, and any changes or differences have been appropriately reviewed and approved by SAHPRA;
- where third-party manufacturing arrangements apply, the documentation establishes a clear and verifiable relationship between the bidder/applicant, manufacturer and product offered; and

- all required regulatory and supporting documentation is submitted in accordance with the requirements of the applicable tender.

The purpose of this clarification is to promote a consistent understanding of the regulatory requirements applicable to complementary medicines and to support transparent and consistent evaluation of these products in national pharmaceutical procurement processes.

Bidders remain responsible for ensuring that the documentation submitted with their bids complies with the requirements of the relevant tender and is sufficient to enable the Department to objectively validate each product offered against the applicable SAHPRA-approved regulatory documentation.