BUSINESS FOR SA | COVID-19

POLICY DOCUMENT

Buyer's guide

Procedure for evaluating potential PPE suppliers

Introduction

Business for South Africa (B4SA) is an alliance of volunteer resources from across South African business bodies and organisations, member companies large and small, including professional services firms. Its mandate is to enable an effective and coordinated response by business, together with other stakeholders, including Government, to the COVID-19 crisis facing South Africa.

In the wake of the coronavirus (COVID-19) crisis, and with the increase in the need for and use of medical devices and equipment to prevent the spread of the coronavirus, including personal protective equipment (PPE), it is paramount that the availability of medical devices and equipment is secured. To this end, B4SA has established a Public Health Workgroup, and within this stream a team has been established dedicated to the sourcing and procurement of PPE and medical devices in accordance with South Africa's legislative and regulatory frameworks.

Purpose of this document and guiding principles

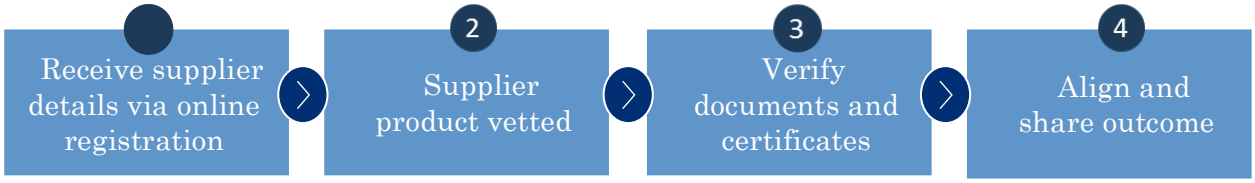
As this team assists in securing PPE and medical device equipment in South Africa, it is paramount that the procedures it uses throughout its sourcing and procurement functions are established, agreed upon, recorded and disseminated to relevant stakeholders.

The purpose of this ***Buyer's Guide*** is to outline the supplier vetting process undertaken by this team as they secure supply of PPE and medical devices for South Africa – across both the public and private sectors. The guiding principles governing the supplier vetting process are:

- **Fairness** – criteria used should be relevant to the purpose of the procurement exercise, and in no way arbitrary or discriminatory;
- **Quality** – criteria used to assess quality should be based on South Africa's legislative guidelines published by relevant authorities, including but not limited to NDoH, SAHPRA, SABS and NRCS and ensure that the product meets the quality standards of the country;
- **Consistency** – criteria used for evaluations should be applied consistently across all suppliers evaluated;
- **Transparency** – criteria should be available to relevant stakeholders to ensure accountability throughout the vetting process, including the storage of vetting outcomes for sharing with a broader audience as required.

High-level overview of the supplier vetting process

The current PPE supplier vetting process contains 4 steps:



Supplier details and applications received through a single, pre-defined online portal

Conditional approval based complete submission and validity of company registration documents

Initial Know your customer (KYC) of supplier done:

KYC checks (including company proof of identity, industry affiliations, tax status)

Conditional approval granted based on relevant certificates submitted

Supplier rejected if sub-standard information/ certificates given

Independent technical vetting team reviews submitted documents against pre-defined vetting criteria to ensure authenticity of submitted regulatory documents and certificates

Suppliers passing technical evaluation are approved by workstream lead and put forward for procurement

Suppliers rejected are notified with reasons, and a list is provided to NDoH, DTI, SAHPRA, Industry Associations and Port Health

Procurement may not take place from rejected suppliers

All vetting outcomes recorded in online supplier database

Detailed steps to be followed across supplier vetting process

Step 1: Confirm submission is complete

- The B4SA team receives the supplier's details through an online portal: https://covid19manager.co.za
    - Initial details recorded by supplier (vendor based identity);
    - Industry membership(s) established;
    - Supplier agrees to code of conduct and records key contact information;
    - Base product brochure uploaded.

Step 2: Supplier vetting (KYC)

- Supplier is vetted by initial KYC team:
    - KYC checks (including company proof of identity, industry affiliations, tax status);
    - Conditional approval granted based on complete company documents submitted;
    - Supplier rejected if detailed information and supporting documents are not provided.
- Supplier conditionally approved and notified that application has been progressed to review of product registrations and certification review.
- Supplier notified to submit pre-determined documentation as would be applicable per product on the online portal:
    - SAHPRA medical device licence;
    - Name and description of product (as per WHO standards for example);
    - ISO 13485 certificate of the manufacturing site;
    - Certification for the product and manufacturing site from SAHPRA aligned authorities such as, but not limited to CFDA, USFDA, EU, TGA, WHO prequalification, etc;
    - Test reports verified by relevant South African regulatory bodies – showing testing of the product against the applicable standard (e.g. WHO, EN ISO, YY, GB);
    - Product specifications and brochure;

- Photo of the product, and its label;
- GMDN numbers;
- NRCS certification;
- SABS test reports.

Step 3: Supplier product vetting

- Check that the supplier has provided their export license issued by the Country of Origin e.g. in light of the recent Chinese Government export regulations.
- SAHPRA license reviewed, including:
  - Ensuring name and address of license holder matches applicatio;n
  - Veracity of license documentation cross-checked with SAHPRA;
  - Ensure license risk category allows for product quoted on to be imported or manufactured.
- If no SAHPRA license is available, and risk categorisation warrants application, then the supplier is asked to apply for a letter of exemption from SAHPRA.
- Review of ISO13485 certificate of manufacturing site (if applicable depending on product type):
  - Ensure name and address of manufacturing site matches application, and has not previously been rejected;
  - Check authenticity of the certificate with the relevant issuing authority;
  - Check validity with conformity assessment body, including expiry date and coverage of product quoted;
  - Check certification covers products quoted for and their specification.
- Review of test reports for each product:
  - Check that the report issued matches the manufacturing site details and type of product quoted;
  - Ensure specifications in test report meet required WHO standards;
  - Check validity with assessment body, including expiry date and batch/UDI.
- Review product certification, accreditation and conformity to standards (if applicable):

    - Check validity with assessment body, including date issued, expiry date, and full product description aligns with product quoted;
    - Check product meets relevant standard (e.g., EN ISO);
    - Contact authorized agent on certificate to confirm validity;
    - Check authenticity of the certificate with the relevant issuing authority.
- Review the product label:
    - To ensure no claims are made beyond its registered specification;
    - Check that it includes the relevant FDA, CE or authority markings and standard declarations.
- For incoming shipments, provisionally approve product pending SABS certification on arrival.
- For invasive machines such as ventilators, follow additional regulatory protocols on clinical and medical review to confirm product has been approved by relevant authorities for use on patients in South Africa.

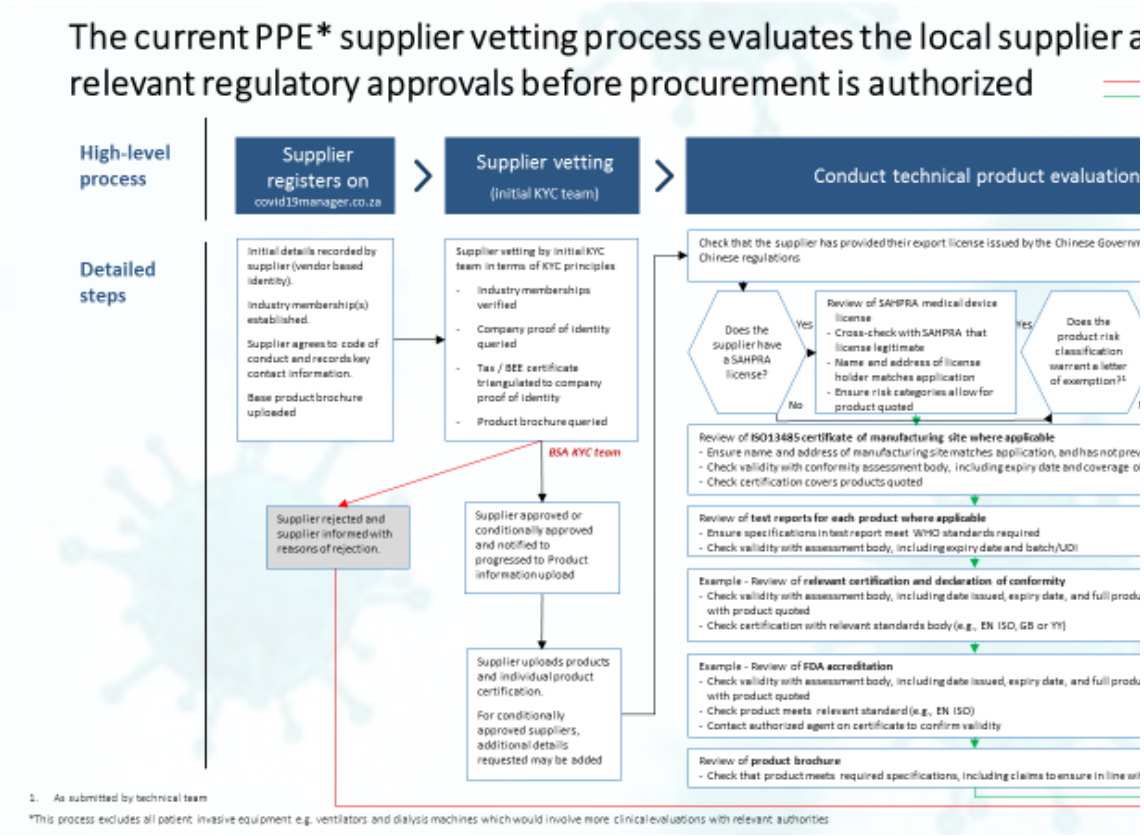
Step 4: Align and share outcome

- If supplier fails evaluation:
    - Update supplier online product list with outcome (rejection) and rationale, including precise evaluation criterion/criteria in which supplier failed;
    - A record of all rejected suppliers and reasons for rejection will be kept on file; If a concern raised with the supplier is rectified, the supplier can start the process all over again;
    - Suspected fraudulent submissions will be handed over to relevant authorities (and blacklisted);
    - The fraudulent products and suppliers to which they are linked will be shared on a weekly basis with SAHPRA, NDoH, Port Health and the DTIC, as well as relevant industry bodies.
- If supplier passes evaluation,
    - Make recommendation to PPE stream lead for supplier approval;
    - Sign-off of supplier approval and any conditions attached to approval;

- Update online supplier product list with outcome (approval) and rationale, including evaluation outcomes across criteria and any exceptions applied;
- Pass supplier details (including quotation) to procurement for financial evaluation and order process;
- For provisional approval of shipments pending SABS certification, inform supplier that procurement process with be finalised upon receipt of relevant quality and standards documentation from SABS;
- Keep records of the list of verified and rejected suppliers (including reasons for rejection), which can be made available on request.

Ends

Exhibit 1 - detailed process flow for supplier evaluation


The current PPE* supplier vetting process evaluates the local supplier a
relevant regulatory approvals before procurement is authorized
High-level process
Supplier registers on covid19manager.co.za
Supplier vetting (initial KYC team)
Conduct technical product evaluation
Detailed steps
Initial details recorded by supplier (vendor based identity).
Industry membership(s) established.
Supplier agrees to code of conduct and records key contact information.
Base product brochure uploaded
Supplier vetting by initial KYC team in terms of KYC principles
- Industry memberships verified
- Company proof of identity queried
- Tax / BEE certificate triangulated to company proof of identity
- Product brochure queried
BSA KYC team
Supplier rejected and supplier informed with reasons of rejection.
Supplier approved or conditionally approved and notified to progressed to Product information upload
Supplier uploads products and individual product certification.
For conditionally approved suppliers, additional details requested may be added
Check that the supplier has provided their export license issued by the Chinese Governm
Chinese regulations
Does the supplier have a SAHPRA license?
Yes
No
Review of SAHPRA medical device license
- Cross-check with SAHPRA that license legitimate
- Name and address of license holder matches application
- Ensure risk categories allow for product quoted
Yes
Does the product risk classification warrant a letter of exemption?1
Review of ISO13485 certificate of manufacturing site where applicable
- Ensure name and address of manufacturing site matches application, and has not prev
- Check validity with conformity assessment body, including expiry date and coverage o
- Check certification covers products quoted
Review of test reports for each product where applicable
- Ensure specifications in test report meet WHO standards required
- Check validity with assessment body, including expiry date and batch/UDI
Example - Review of relevant certification and declaration of conformity
- Check validity with assessment body, including date issued, expiry date, and full produ
with product quoted
- Check certification with relevant standards body (e.g., EN ISO, GB or YY)
Example - Review of FDA accreditation
- Check validity with assessment body, including date issued, expiry date, and full produ
with product quoted
- Check product meets relevant standard (e.g., EN ISO)
- Contact authorized agent on certificate to confirm validity
Review of product brochure
- Check that product meets required specifications, including claims to ensure in line wi
1. As submitted by technical team
*This process excludes all patient invasive equipment e.g. ventilators and dialysis machines which would involve more clinical evaluations with relevant authorities