Guidance for suppliers of hand sanitisers

Guide on the key aspects that suppliers of hand sanitisers should pay attention to, when assessing the product's safety, quality and efficacy.

Below are the key aspects that suppliers should pay attention to, when assessing the product's safety and quality. However, as this is not an exhaustive list of pointers, suppliers have to include any other areas where appropriate.

1. Local suppliers' responsibilities

As the person introducing the hand sanitisers into the local market, all suppliers (i.e manufacturers, importers, wholesale dealers, and sellers) are to ensure that the products manufactured, imported or sold are safe, of appropriate quality and efficacious, and meet the criteria set out in the topical antiseptic guidelines before supply. The details of guidelines are available on our website at https://www.hsa.gov.sg/topical-antiseptics/overview

Generally, suppliers should check product alerts posted on the HSA website so that you do not unwittingly bring in products that have reported safety and quality issues such as product defects. Suppliers must ensure that the product is not harmful or unsafe and conforms to the applicable pharmacopoeia standards for topical antiseptics before supplying them in Singapore.

To avoid dealing with sub-standard or unsafe products, suppliers are advised to:

- be cautious with solicitations from unknown distributors or suppliers who advertise via email blasts or online platforms; and
- be wary if the pricing of the product or raw materials sounds too good to be true.

2. Sourcing from reliable suppliers

It is important to work with reputable and reliable suppliers so that they will not supply active ingredients, raw materials or finished products of dubious quality to you. Unscrupulous suppliers may also sell to you raw materials or products that have been added or substituted with undeclared substances that are harmful to human health.

You should look into the following aspects to help assess the reliability of your suppliers:

- Suppliers who operate their business activities legitimately in countries where they are located;
- Manufacturers have been audited and certified by the relevant regulatory authority to be compliant with Good Manufacturing Practice (GMP) according to the Pharmaceutical Inspectorate Cooperation Scheme (PIC/S) standard and possess a valid GMP certificate; and
- Suppliers have checks in place to ensure that the raw materials or finished products meet pharmacopoeia standards; and

In addition, it will also be useful to visit the supplier's warehouse and if possible, the manufacturer's facilities to establish if there are proper systems and facilities available in handling the products. You may consider engaging a competent consultant to assist in the assessment.

3. Ensuring product safety

3.1 Product Formulation

Suppliers have to check the full product formula to ensure that the ingredients used in the products are safe and meet the requirements published on the HSA website: https://www.hsa.gov.sg/topical-antiseptics/overview

3.2 Product Testing

Manufacturers should test the raw materials used and ensure that the raw materials comply with the pharmacopoeia standard before manufacture. In addition, the manufacturer should test every batch of finished product to ensure the product meet product specifications and pharmacopoeia standards and provide the Certificate of Analysis (CoA) to the purchasers.

Local suppliers should request the Certificate of Analysis (CoA) from your supplier (local or overseas manufacturer, importer) for every batch of finished product to show the finished product meets the manufacturer's product specifications and pharmacopoeia standards. On top of the test reports that provided by your suppliers, local suppliers should institute checks to confirm the product's quality as added assurance. This is to check and verify the test results of the manufacturer, especially when the manufacturer is not a PIC/S certified GMP manufacturer. Importers should conduct your own product testing at accredited laboratories.

Please refer to the website of the Singapore Accreditation Council (SAC) for the list of local laboratories accredited to conduct testing of the chemicals used in hand sanitisers. Suppliers

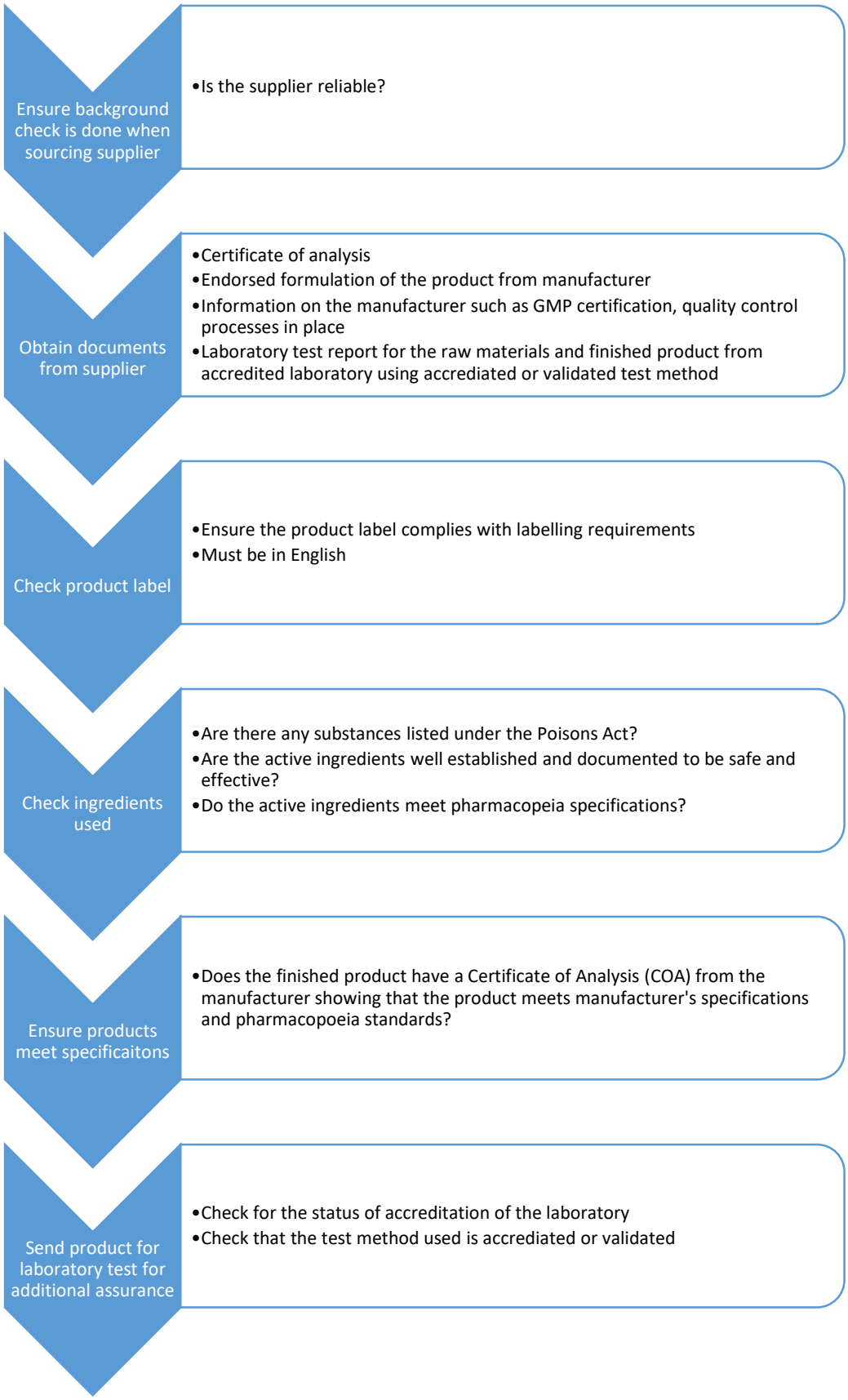
may seek assistance from contract laboratories on the appropriate tests to be conducted, based on the product uses and formulation.

Suppliers are also advised to discuss with your contract laboratories and request them to highlight to you if there are anomalies observed from the testing outcome, even if they fall outside the targeted scope. For example, any unusual peaks found in the chromatogram that may potentially indicate the presence of other contaminants/adulterants, which should be further investigated.

4 Documentation and Records Keeping

Suppliers should maintain documentation of the CoA from your suppliers for every batch supplied as well as any test reports conducted by accredited laboratories. Supply records should also be maintained for product traceability. HSA may request such documentation and records for review when conducting post-market checks.

CHECK LIST FOR SUPPLIERS TO ENSURE COMPLIANCE OF HAND SANITISERS



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