Office of the National Director of Procurement
Health Business Services
Health Service Executive
Dr. Steevens' Hospital
Dublin 8
D08 W2A8

Oifig an Stiúrthóir Náisiúnta Soláthair
Seirbhísí Gnó Sláinte
Feidhmeannacht na Seirbhíse Sláinte
Ospidéal Dr. Steevens'
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Deputy Róisín Shortall,
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

09/11/2020

RE PQ 33915/20

Question

To ask the Minister for Health the steps he is taking to ensure that all sanitising products supplied by the HSE are in compliance with recognised standards; and the safety assessment a product ViraPro was put through prior to the product being purchased and supplied to healthcare outlets - Róisín Shortall. -Róisín Shortall

Response

Deputy O Snodaigh,

The Health Service Executive (HSE) has been requested to reply directly to you in the context of the above Parliamentary Question which you submitted to the Minister for Health for response.

The following procedure is applied to any Supplier offering a PPE product including all Hand Sanitising products;

- Supply offers come through many channels but are all directed to our sourcing team where supplier's details and products they wish to supply are logged on our 'Leads Log'.
- All products must comply with the WHO specification which lists appropriate standards by product type
- Suppliers are provided with a Quotation Form and a Decision Support Model (DSM) both tailored to the product type. The DSM requires the supplier to provide details of the product offered including manufacturer details, plus details of the exporter (where applicable) and whether the appropriate export licences are held. It also outlines the standards that type of product must conform to and the documentation required to be provided before their offer can proceed onto the Quality Assurance (QA) stage. This usually includes Declaration of Conformity to relevant CE standard, Notified Body Cert (where applicable), tests/lab reports demonstrating conformity to the EN standards, pictures of the product and packaging and any other requirements specific to that product. If it is a product being exported from China, there is a check to see if it is on the register (either List of NMPA-approved Manufacturers of PPE and Medical Devices or Chinese Chamber of Commerce list) and can be exported.
- Once all required documentation has been received it is forwarded to the Quality Assurance Lead in the COVID-19 Procurement Team who checks all documentation has been provided and is valid. e.g. Certs numbers are checked against notified body registers to ensure they are legitimate. Products that come under Medical Devices Directive Class 1 require a Declaration of Conformity. Products that come under the PPE legislation require a Certificate from a notified body whose scope of certification includes PPE. All test reports are checked to ensure they meet the parameters of the required standard.

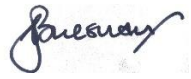
- QA Lead is in regular contact with HPRA & Health & Safety Authority, who are available to assist when regulatory queries arise.
- Quality Assurance Lead deems the product a Pass/Fail. A Pass is dependent on all documentation being provided to demonstrate product meets the specification. If it does not pass, supplier is informed what documentation is missing/required should they wish to progress their offer.
- All new products arriving to the warehouse are photographed and quarantined and placed on a quarantine register and are subject to a number of checks including a check to see that the product delivered is the same as the one ordered. A unique reference number is assigned to the product on the product register and warehouse system.
- Before issue, status of the product is checked to see that all the quality documentation is in order and if any additional QA is required. Samples of products are reviewed by QA Lead and where QA Lead deems it necessary (eg masks) a sample of the product is sent to a nominated individual within the Antimicrobial Resistance and Infection Control (AMRIC) for clinical suitability assessment. A product may be recommended as suitable for use, not preferred or not suitable for healthcare use following this assessment. Once warehouse have been informed that product is approved, they release stock from quarantine and it can be issued into the system.

The HSE can confirm that all hand sanitiser in stock and available for delivery to healthcare facilities is fully compliant with WHO Guidelines are listed on DAFM Biocidal Register. In addition to the above steps, HSE is currently in discussions with Dept Agriculture Food & Marine with a view to having samples of all brands of hand sanitiser tested for compliance with the relevant standards.

With specific reference to ViraPro Hand Sanitiser, the Material Safety Data Sheet was submitted by the supplier prior to purchase. Both the MSDS and product label outlined a minimum 75% alcohol content, which is fully in compliance with the WHO Guidelines.

I trust this information is of assistance to you, but should you have any further queries please do not hesitate to contact the Office of the Head of Procurement on (01) 635 2251 or via ohop@hse.ie.

Yours sincerely,



Sean Bresnan| **National Director of Procurement** | HSE | 2nd Floor | Dr. Steevens' Hospital | Dublin 8 | D08 W2A8 |