# NATIONAL ASSEMBLY

**FOR WRITTEN REPLY**

**QUESTION NO. 1328**

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**(INTERNAL QUESTION PAPER NO. 13)**

**Mrs M B Hicklin (DA) to ask the Minister of Health:**

(1) Whether, with reference to his reply to question 856 on 15 April 2021, healthcare workers were made aware of the fact that the K95 masks presented to them only had a very low filtration-efficacy range and could compromise their own health; if not, why not; if so, what are the relevant details;

(2) what consequence management will be meted out to the (a) procurers and (b) suppliers of the specified masks?

###### NW1524E

**REPLY:**

1. The respirators that did not meet the minimum standard as per the laboratory test were not distributed to health care workers. Where the respirators were distributed these were immediately removed from circulation on instruction to the head of the institution and replaced with respirators that complied with the minimum standard. Communication was sent out to hospitals that received a consignment of donated KN95 that had to be recalled. In this instance the donor replaced the respirators with a new consignment.
2. The National Department of Health: Policy for the Regulation of Quality Respiratory Protective Equipment (RPE) Supply in Healthcare, August 2020 makes the following provision, in accordance with SAHPRA requirements, for all licensed establishments to conduct post marketing surveillance:

*“*Prior to use of respirators purchased, a minimum of 10 respirators per 1000 (or part thereof) and at least 100 units of 10000 should be randomly picked by the purchaser from the boxes in their possession and sent at a minimum for a Particulate Filter Penetration test at a published accredited South African test laboratory (to sodium chloride) which test must indicate that the respirator has passed the minimum specification. This cost is borne by the seller (incorporated into cost of sale) and selection of respirators for testing is conducted by the purchaser to maintain integrity of random selection, testing and reporting to the purchaser.

* 1. If respirators pass this test, all respirators in the same production batch may be used, in the same purchase and having been delivered, and in possession of the purchaser.
  2. Failed tests require a second batch of randomly selected (or the same) respirators be sent for formal testing as per point 6.
  3. The final result of the testing must be reported to the supplier and a copy supplied to SAHPRA and the NRCS. The supplier is then required by the regulators to report (as per pharmaceutical batch recalls), on a publicly accessible portal for the particular batch affected (as per many other global regulatory agency standards for quality testing) at a minimum on SAHPRA and NRCS websites (or a link from one to the other).
  4. Publication will only reference the manufacturer, batch failed and test results. The implication should not necessarily be that all respirators from the manufacturer are defective.”

END.