# NATIONAL ASSEMBLY

**FOR WRITTEN REPLY**

**QUESTION NO. 2398**

**DATE OF PUBLICATION IN INTERNAL QUESTION PAPER: 16OCTOBER 2020**

**(INTERNAL QUESTION PAPER NO. 38)**

**Ms M D Hlengwa (IFP) to ask the Minister of Health:**

(1) What (a) total number of the suppliers of the government-wide Covid-19 tender were unlicensed by the SA Health Products Regulator to provide medical devices therefore not subject to regulatory oversight and (b) are the names of the specified suppliers and their board of directors;

(2) (a) what total number of the unlicensed suppliers supplied class A low risk and class B low-moderate risk medical devices and (b) did any unlicensed suppliers provide class B medical devices to hospitals;

(3) whether any amendments to procurement guidelines and medical regulations were made to facilitate the awarding of contracts to unlicensed providers; if not, what is the position in this regard; if so, what measures were taken to ensure that the amendments were monitored and enforced?

###### NW2973E

**REPLY:**

(1) (a) The awarding of tenders to supply Personal Protective Equipment (PPE) for COVID-19 does not fall within the mandate of the South African Health Products Regulatory Authority (SAHPRA) therefore, SAHPRA does not have record of the unlicensed suppliers in this regard. SAHPRA publishes a list of licence holders who are authorised to manufacture, distribute (including import and export) and wholesale medical devices and in-vitro medical devices (IVDs). This list is available on the SAHPRA website which can be accessed at this address: [www.sahpra.org.za](http://www.sahpra.org.za)

(b) SAHPRA does not have record of the names of government-wide unlicensed suppliers for PPE tenders and their Board of Directors.

(2) (a)-(b) Not applicable to SAHPRA. The Entity does not have record of unlicensed suppliers who were awarded tenders to supply Class A and Class B medical devices to hospitals.

(3) There were no amendments made to the guidelines and regulations made in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended, to facilitate the awarding of contracts to unlicensed providers. SAHPRA has published a series of communication documents during the pandemic to communicate the existing regulatory requirements and processes to stakeholders in accordance with SAHPRA’s mandate.

END.