# NATIONAL ASSEMBLY

**FOR WRITTEN REPLY**

**QUESTION NO. 759**

**DATE OF PUBLICATION IN INTERNAL QUESTION PAPER: 10 MARCH 2023**

**(INTERNAL QUESTION PAPER NO. 08)**

**Mrs M O Clarke (DA) to ask the Minister of Health:**

Whether the SA Health Products Regulatory Authority is allowing the importing of Meloxicam BP for other (a) purposes and/or (b) companies besides certain companies (names furnished); if not, what is the position in this regard; if so, to which other companies? **NW858E**

**REPLY:**

1. Based on response received from the South African Health Products Regulatory Authority (SAHPRA), the importation of Meloxicam is allowed as a substance by companies that are licenced to (a) import as per Section 22C (1)(b) of the Medicines Act and Regulation 6 of the regulations published in terms of the Medicines Act.

There are requirements in terms of the possession, manufacture or selling of a scheduled substance. Section 22A (1) of the Medicines Act, states that no person shall sell, have in his or her possession or manufacture any medicine, Scheduled substance, medical device or IVD, except in accordance with prescribed conditions. Section 22A(5) further provides conditions regarding the sale of schedule 3 and mentions the persons that may sell these substances. Persons allowed to sell Schedule 3 substances include registered pharmacy personnel, manufacturers, wholesalers and other health care professionals that are adequately licensed in terms of Section 22C(1)(a) of the Medicines Act.

SAHPRA requires substances to be sold according to the requirements of the Medicines Act and its regulations. It should be noted that Meloxicam is not subject to the requirements of Schedule 3 when it is specifically packed, labelled or sold for industrial purposes including the manufacture or compounding of consumer products which have no pharmacological action or medicinal purpose, or if used for analytical laboratory purposes.

(b) SAHPRA regulates persons who are licensed to import scheduled substances and its mandate includes enforcing the requirements of the Medicines Act in terms of control of scheduled substances for medical use. SAHPRA does not regulate companies involved in the use of meloxicam for industrial purposes including the manufacture or compounding of consumer products which have no pharmacological action or medicinal purpose, or if used for analytical laboratory purposes.

END.