# NATIONAL ASSEMBLY

**FOR WRITTEN REPLY**

**QUESTION NO. 612**

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**(INTERNAL QUESTION PAPER NO. 06)**

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

Considering that the SA Health Products Regulatory Authority is blocking companies (details furnished) from importing Meloxicam BP for compounding purposes, despite the fact that SAHPRA’s reasoning is apparently based on a faulty interpretation of the law (details furnished), what are the reasons that SAHPRA is blocking the importing of Meloxicam BP for compounding purposes? **NW683E**

**REPLY:**

According to the South African Health Products Regulatory Authority (SAHPRA), the importation of Meloxicam was not blocked. Meloxicam is a scheduled substance, and the importer of these substances requires an importation licence as per Section 22C (1) (b) of the Medicines Act and the related regulations.

The SAHPRA processes all applications in accordance with the legislation indicated above and has presence at the regulated ports of entry in line with Regulation 6 of the Regulations, to ensure that the importers of scheduled substances comply with the law. As per the table below there is no Meloxicam detained as per the list of importers provided in the question:

**TABLE 1: IMPORT LICENCE APPLICATION STATUS OF FURNISHED COMPANIES**

| **No** | **Company** | **Import Licence Application Status** | **Currently Detained API** | **Expected Outcome date** |
| --- | --- | --- | --- | --- |
| 1 | DB Fine Chem/ Spec | Application finalised recently Licence to Import/distribute scheduled substances as per approved list and pharmacies offering compounding services may access via this or similarly licenced facility. | None | N/A |
| 2 | Marsing | Licence being finalised, due to name change and organisational ownership changes over the past few years, they were delaying on application processes. This has now been resolved. | None | N/A |
| 3 | Idexis | No application received | Under review Vitamin K2 (ORTIA) | Before 9/03/2023 |
| 4 | Compounding Pharmacy of SA | No application received | None | N/A |
| 5 | Fagron | No application received | None | N/A |
| 6 | Rowan Management | No application received | None | N/A |
| 7 | V Tech | Licence application under process due to other considerations and an inspection to take place | Under review prednisolone (ORTIA) | Before 9/03/2023 |
| 8 | Acupharm | No application received | Under review Famotidine (ORTIA) | Before 9/03/2023 |
| 9 | Lycoderm | No application received | Under review Vit K1(through Multichem Sourcing ORTIA) | Before 9/03/2023 |
| 10 | Lenbury | No application received | None | N/A |
| 11 | Kyron | No application received | Under review Petcam (ORTIA) | Before 9/03/2023 |
| 12 | Avanti | No application received | None | N/A |
| 13 | Vets Focus | No application received | None | N/A |

END.