# NATIONAL ASSEMBLY

**FOR WRITTEN REPLY**

**QUESTION NO. 1275**

**DATE OF PUBLICATION IN INTERNAL QUESTION PAPER: 14 MAY 2021**

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

**Ms H Ismail (DA) to ask the Minister of Health:**

(a) Whether he will furnish Ms H Ismail with a full report on the Ivermectin controlled-access programme and (b) how long is it envisaged that the review programme for the applications of patients will take before Ivermectin will be allowed to be used?

###### NW1468E

**REPLY:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1. Ivermectin Authorisation Status 25/05/2021 | | | | |  |
|  |  |  |  |  |  |
|  | **Approved** | **Rejected** | **Pending** | **Duplicate** |  |
| **Tier 3: Section 22C(1)(b) - licence holder** | 8 | 3 | 0 | 0 |  |
| **Tier 2: Healthcare Facility Stock** | 134 | 40 | 0 | 4 |  |
| **Tier 1: Named-patient** | 112 | 15 | 0 | 2 |  |
| **TOTAL** | 254 | 58 | 0 | 6 | **318** |

1. The use of Ivermectin in the treatment and prevention of COVID-19 infections received avid interest recently due to the antiviral and anti-inflammatory properties in vitro. Available data to date, mostly from small under-powered studies, show a trend towards some benefit in the management of COVID-19. National and international bodies have reviewed the data; and have concluded that there is unclear evidence of both benefit and harm, in the treatment and prevention of COVID-19. After consideration of the impact of the second wave as well as the clinical equipoise that was presented through the various studies reviewed, SAHPRA implemented an Ivermectin Controlled Compassionate Use Programme for approved unregistered ivermectin products to be accessed via a three-tier programme for Section 22C(1)(b) permit holders, healthcare facilities, and named-patient applications. On 16 March 2021,SAHPRA registered Soolantra 10mg/g cream formulation, which contains ivermectin. Soolantra Cream is indicated for the topical treatment of moderate to severe inflammatory lesions of papulopustular rosacea in adult patients and is not for the prevention or treatment of COVID-19. The registration of this product enabled the compounding of ivermectin on a prescription basis for specific patients as well as off label use of ivermectin under the section 21 Controlled Compassionate Use Programme.

END.