# NATIONAL ASSEMBLY

**FOR WRITTEN REPLY**

**QUESTION NO. 2735**

**DATE OF PUBLICATION IN INTERNAL QUESTION PAPER: 07 DECEMBER 2016**

**(INTERNAL QUESTION PAPER NO. 43)**

**Dr H C Volmink (DA) to ask the Minister of Health:**

(1) What do practitioners of Chinese Medicine and Acupuncture, registered with the Allied Health Professions Council of South Africa, require in order to import single (a) raw and/or (b) powdered Chinese herbs for medicinal purposes and dispensing;

(2) whether there are any labelling requirements for the specified single Chinese herbs; if not, why not; if so, what are the relevant details;

(3) whether any prohibitions exist for importing single Chinese herbs for use by the specified practitioners; if so, what are the relevant details?

###### NW3223E

**REPLY:**

(1) The Medicines and Related Substances Act, 1965 (Act 101 of 1965) controls the sale of medicines. In accordance with Regulation 25 of the Act, medicines are categorised into four categories of which category D refers to Complementary Medicines intended for use in humans and animals.

 The Council has identified 5 disciplines of Complementary medicines of which Chinese Traditional Medicines is but one.

 The Medicines Control Council (MCC) regulates the use of any active ingredient to be used in a medicine by means of the registration process of the medicines. During the registration process, the MCC will consider the quality, safety and efficacy of the active ingredient/herb to be included in the medicine.

 The MCC will allocate a Schedule status to the active substance contained in the herb. The scheduling status of the substance will determine the import requirements that the Chinese medicine practitioner needs to comply with. In the event that the substance is listed as a specified Schedule 5, Schedule 6 or Schedule 7 substance, the importing practitioner requires an import permit from the Director-General: Health (Section 22A (11) of the Act). Substances listed as S0, S1, S2, S3 or S4 may be imported by a practitioner without any restriction.

(2) Labelling requirements: in terms of the MCC requirements relating to Good Manufacturing Practices (GMPs) for the manufacture of a medicine, the guidelines specify the requirements to be included on the label of any raw material. The following information is the minimum information required:

* Name of the substance
* Chemical name of the substance
* Batch number
* Expiry date
* Name of the manufacturer of the substance / herb
* Indication of the hazardous nature of the substance
* Quantity
* Warning: requirement to protect against moisture or light
* Storage conditions

(3) Prohibition on the importation of a herbal substance relates to the scheduling status of the substance. See response in (1) above.

END.