WORLD TRADE ORGANIZATION

G/LIC/Q/BGD/4

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Committee on Import Licensing

Original: English

NOTIFICATION UNDER ARTICLES 1.4(A) AND 8.2(B) OF THE AGREEMENT ON IMPORT LICENSING PROCEDURES FROM BANGLADESH[1]

REPLIES FROM BANGLADESH TO QUESTIONS FROM THE UNITED STATES[2]

The following communication, dated 25 September 2013, is being circulated at the request of the delegation of Bangladesh.

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(i) In accordance with Article 7.3 of the Import Licensing Procedures Agreements, Bangladesh made notification in 2007 regarding the abolition of the Import Licensing system. However, Bangladesh is taking steps to fulfill its notification obligation in this regard.

(ii) Bangladesh would like to place the following facts as regards to the observations and questions made in the para. 3 and 4:

(a) What is the status of this 1998 directive of the Prime Minister? Is it still being implemented?

- There is a committee named Standing Committee for Import of Pharmaceuticals constituted by the Ministry of Health & Family Welfare, The Government of the People's Republic of Bangladesh. This committee accord approval for importation of drugs & medicines assessing their requirements. Yes, 1998 directive of the Prime Minister is still being implemented. We encourage technology transfer of recently innovated life savings drugs from the research based pharmaceuticals.

(b) Please describe the purpose of "Indent" requests submitted to the Director General of Drug Administration (DGDA), the basis for approving indent requests; and, what the procedures and requirements are for obtaining an indent.

- The purpose of "Indent" requests submitted to the Director General of Drug Administration is for getting prior approval to import registered products on the basis of country demand.

- The importer submit indent of the registered products as per prescribed From of Directorate General of Drug Administration. It is then placed before the Standing Committee meeting for Import of Pharmaceuticals who evaluates the need & importance of the products to be imported and if satisfied accords indent approval. After getting approval of an indent, the importer opens a Letter of Credit with the bank. When the consignment of drugs arrives in the country they need clearance from the DGDA to release the drugs from the Custom Authority.

(c) We understand that importers are required to obtain an indent in order to import medicines. Are local producers required to obtain such approval?

- Yes, Local producers also need to get such approval to import Drug Substances.

[1] G/LIC/N/1/BGD/1.
[2] G/LIC/Q/BGD/1.

(d) What is a certificate of registration from the Directorate of Drug Administration? Who is required to obtain such registration? Is such registration required before Bangladesh will allow imports of pharmaceuticals into the market?

- Certificate of registration of a product means permission from the DGDA to manufacture for sale or import of medicine. According to Section 5(1) of Drug Control Ordinance 1982, Registration is mandatory for manufacture for sale or import of medicines. The section 5(1) of Drug Control Ordinance is –"No Medicine of any kind shall be manufactured for sale or be imported, distributed or sold unless it is registered with the Licensing Authority."

(e) How long does the process take to receive a certificate of registration and an indent?

- For introduced it takes six month and for unintroduced molecule it takes none month to one year to receive a certificate of registration. In case of indent it usually takes one month for approval.

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