



PERMANENT MISSION OF THE KINGDOM OF BHUTAN
TO THE UNITED NATIONS

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PMB/UN/INCB

The Permanent Mission of Bhutan to the UN & Other International Organisations presents its compliments to the UN International Narcotics Control Board in Vienna and has the honour to convey the following in pursuant of UNINCB Circular Ref. No. E/INCB/PSY/C.L.8/2005 dated 10/2/05 :

"With regard to legal or administrative measures adopted to allow travellers leaving/entering the country to carry medical preparations containing controlled substances for personal use, Clause No. 16, Part IV of our Medicine Rules & Regulations underlines the possibility for travellers to carry medicinal preparations, including those containing controlled substances, for personal use. The Regulations are still in the final Draft form awaiting endorsement by the Bhutan Medicines Board. A copy of the relevant part of the Regulations is attached for information."

64

The Permanent Mission of Bhutan avails itself of this opportunity to renew to the UN International Narcotics Control Board the assurances of its highest consideration.

GENEVA, 12 April 2005

Treaty & Legal Affairs Division,
International Narcotics Control Board,
Vienna.

Travellers



INCB PSYCHOTROPICS UNIT		
Action: File: <i>DEC. 80-54 (BHU)</i>		
10 MAY 2005		
	Name	Date
Drafted		
Cleared		

Hausa

SECRETARIAT OF THE INCB	
RECEIVED	
- 2 MAY 2005	
ACKNOWLEDGED	

PART IV

AUTHORIZATION FOR IMPORT

- 14.0 **Application for Import Authorization:**
- 14.1 An application for an authorization to import medicinal product shall be made to the Authority in Form II, accompanied by a token fee (refer part XXI).
- 14.2 A single application may be made and an authorization may be issued in respect of import of more than one drug manufactured by the same manufacturer.
- 14.3 Only the individual or group of individuals or organization that is authorised by the Authority shall be permitted for import of any medicinal product.
- 14.4 An import authorization for medicinal products shall be issued in Form IIA.
- 14.5 An application for special import authorization shall be made in Form VIII for import of controlled and restricted drugs under Schedule C1 and Schedule C2
- 14.6 An import authorization for controlled and restricted drugs shall be issued in Form VIIIA and valid for a single import for three months.
- 14.7 Import license shall be issued by a relevant agency only upon the presentation of the import authorization from the Authority.
- 14.8 Import authorization is not a substitute for import licence.
15. **Conditions for issuance of import authorization:**
- 15.1 An import authorization shall be issued only if:
- 15.1.1 the applicant is either a Competent Person or has a Competent Person employed to supervise and monitor the sale and distribution of medicinal products;
- 15.1.2 all the necessary documents as specified in the Form II are attached along with the application;
- 15.1.3 the Authority is convinced that there is a licensed premise where the imported drugs will be stored before sale and distribution;
- 15.1.4 the applicant shall maintain records and inform the Authority of all particulars of products including product specifications, quantities imported, date of importation and to whom sold.

- 15.2 The applicant shall provide unhindered access to an Inspector authorised by the Board or Authority to enter with or without prior notice and inspect the premises where the imported products are stored.
- 15.3 Import authorization for vaccines and biologicals shall be issued only if the conditions prescribed under schedule F of the regulation is complied with.
- 15.4 A special import licence or permit shall be issued by the relevant agencies for importation of narcotic drugs and psychotropic substances listed under Schedule C1 and Schedule C2 of the Regulation, based on the special import authorization issued by the Authority in Form VIIIA.
- 16.0 **Import of medicines for personal use:**
- 16.1 Any person who wishes to bring into the country any medicinal product listed under schedule A, shall be allowed in a quantity not exceeding the quantity required for one month, or
- 16.2 in case of prescription drugs, the provision under Section 26 (i) of the Act shall be applicable only in case of suspected criminal activities, or
- 16.3 any person who has a prior approval from the Authority or prescription is exempted from the requirement of an import licence; the authorization shall be issued in Form IIB.