Guidance Document

(Medical Devices and Diagnostic Division)

Title: Guidance Document on Common Submission Format for Import of Notified Diagnostics Kits in India

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CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
DIRECTORATE GENERAL OF HEALTH SERVICES
MINISTRY OF HEALTH & FAMILY WELFARE
GOVT. OF INDIA

Notice:

This Guidance Document is aimed only for creating public and stakeholder's awareness about In-Vitro Diagnostic Devices Regulation by CDSCO and is not meant to be used for legal purposes. The readers are advised to refer to the statutory provisions of Drugs and Cosmetics Act & Rules and respective Guidelines / Clarifications issued by CDSCO time to time for all their professional needs.

CDSCO

Table of Contents

A. Preface:

In India import, manufacturing, sale and distribution of Notified Diagnostics Kits are regulated under Drugs and Cosmetics Act, 1940; and Rules, 1945. At present following notified Diagnostics Kits are regulated under the said Act & Rules.

1. In vitro Diagnostics Devices for HIV, HBV and HCV.
2. In vitro Diagnostics Devices for HIV, HBV and HCV (Bulk)
3. In vitro Blood Grouping Sera
4. In vitro Blood Grouping Sera(Bulk)

The proposed requirements for the regulatory control over notified Diagnostics Kits are being uploaded for the information of all stakeholders.

The document is intended to provide guidance for use in the import of notified Diagnostics kits in India.

This guidance document will be effective from **15/11/2013.**

B. Requirements for Common Submission Format for Import Licence of Notified diagnostic kits in India

The following documents are required to be submitted in the following manner and order for issue of the Import Licence of the **Notified diagnostic kits** for import into India: -

1. **Covering Letter** – The covering letter is an important part of the application and should clearly specify the intent of the application (whether the application for the Import Licence of the proposed kit is being submitted for the first time or the application is for renewal). The list of documents that are being submitted (Index with page no's) as well as any other important and relevant information may be provided in the covering letter. The covering letter should be duly signed and stamped by the authorized signatory, indicating the name & designation of the authorized signatory mentioning Email-Id, Fax no. along with the name and address of the firm.

2. An **Authorization letter** in original issued by the Director/Company Secretary/Partner of the Indian Agent firm revealing the name & designation of the person authorized to sign (along with the name and address of the firm) legal documents such as Form 8 and Form 9 etc. on behalf of the firm should be submitted at the time of submission of the application for Import Licence Duly attested photocopies of the Authorization letter may be submitted at the time of submission of subsequent applications.

3. A duly filled **Form 8** (Application for license of import drugs (excluding those specified in Schedule X) to the Drugs and Cosmetics Rules, 1945) as per the Performa prescribed in the Drugs & Cosmetics Rules, signed & stamped by the Indian Agent along with name & designation of the authorized signatory. Form 8 Performa is enclosed at **Annexure - I**.

4. A duly filled **Form 9** as per the Performa prescribed in the Drugs & Cosmetics Rules, signed & stamped by the Indian Agent along with name & designation of the authorized signatory or Duly Apostle/Attested by the Indian Embassy in the country of origin, if Signed and stamped by the Manufacturer along with name & designation of the authorized signatory. Form 9 Performa is enclosed at **Annexure – II.**

5. The **Requisite Fee** as prescribed in the Drugs & Cosmetics Act & Rules viz. ₹ 1000 for One proposed Device and ₹ 100 for each additional kit to be imported may be submitted at notified branches of Bank of Baroda under the Head of Account "0210 - Medical and Public Health, 04 - Public Health, 104 - Fees and Fines" adjustable to Pay and Account Officer, DGHS, New Delhi in the form of a Treasury Challan. Performa for Treasury Challan (TR 6) is annexed at **Annexure - III**. The Receipt in original (TR 6) is required to be submitted along with the application for Import Licence.

In case of any direct payment of fee by the manufacturer in the country of origin, the fee shall be paid through Electronic Clearance System (ECS) from any bank in the Country of Origin to the Bank of Baroda, Kasturba Gandhi Marg, New Delhi, through the electronic code of the bank in the Head of Account stated above and the original receipt of the said transfer shall be treated as equivalent to the Bank Challan, subject to the approval by the Bank of Baroda that they have received the payment.

6. A duly attested /notarized (in India) and valid copy of **Wholesale License** for sale or distribution of drugs under Drugs and Cosmetics Rules **in Form 20B & 21B** or its renewal in **Form 21C** issued by the State Drug Licensing Authority.

Or

Duly attested and valid copy of Manufacturing License issued by the State Drug Licensing Authority in case the Indian Manufacturer is importing the kits in bulk form for further processing.

7. A Valid copy of **Registration Certificate** in Form 41 issued by CDSCO with respect to proposed kit.

8. The required documents as per condition(s) of Registration Certificate in Form 41 issued by the CDSCO. (If Applicable)

9. A copy of the Import license in Form 10 issued by CDSCO with respect to proposed products.(if the application is for Renewal / Endorsement)

NOTES:

- *Name and address of the manufacturer, Name and address of the manufacturing premises, Name and address of the Indian Agent and Name of the Notified diagnostic kit(s) proposed to be imported should correlate with the name mentioned in Form 8 , Form 9, Form-41.*

- *For endorsement to an existing license, a copy of existing Form 10 License and it`s endorsements, if any should be furnished along with the application.*
- *Application for fresh import license should be made three months before the expiry of the existing import license. The original form-10 should be submitted along with application in such cases.*
- *In case the same import license number is to be issued, the same should be mentioned in the covering letter.*

II. Annexures

Annexure I Format for Form 8

Annexure II Format for Form 9

Annexure III Format for TR6 Challan

ANNEXURE – I

FORM 8
(See rule 24)
Application for license to import drugs (excluding those specified in Schedule X) to the Drugs and Cosmetics Rules, 1945

I/We*..... (Name, full address with telephone, fax and E-mail address) hereby apply for a license to import drugs specified below manufactured by M/s..... (Name, full address with telephone, fax and E-mail address).

2. Names of the Drugs to be imported:

S. No.	Name of the Product		Specific Intended use
	Generic Name	Brand Name	

3. I/We* ..... enclose herewith an undertaking in Form 9 dated …… signed by the manufacturer as required by rule 24 of the Drugs and Cosmetics Rules, 1945.

4. I/We* ..... enclose herewith a copy of Registration Certificate concerning the drugs to be imported in India, issued under Form 41 of the rules, vide Registration Certificate No.....dated ..... issued through M/s. .....(Name, full address with telephone, fax and E-mail address).....valid up to..... .

5 I/We*..... hold a valid wholesale license for sale or distribution of drugs or valid license to manufacture drugs, under the provisions of the Act and rules made thereunder. A copy of the said license is enclosed.

6. A fee of.....has been credited to Government under the Head of Account "0210- Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the Drugs and Cosmetics Rules, 1945 - Central vide Challan No..... dated..... (Attached in original)

Place: _____
Date: _____

Signature of the
Manufacturer's Agent in India
(Name & Designation)
Seal / Stamp

*Delete whichever is not applicable.

ANNEXURE – II

FORM 9
(See rule 24)
Form of undertaking to accompany an application for an import license

Whereas ..... of..... Intends to apply for a license under the Drugs and Cosmetics Rules, 1945, for the import into India, of the drugs specified below manufactured by us, we……of……..hereby give this undertaking that for the duration of the said license—

(1) The said applicant shall be our agent for the import of drugs into India;

(2) We shall comply with the conditions imposed on a license by 1[rules 74 and 78] of the Drugs and Cosmetics Rules, 1945;

(3) We declare that we are carrying on the manufacture of the drugs mentioned in this undertaking at the premises specified below, and we shall from time to time report any change of premises on which manufacture will be carried on and in cases where manufacture is carried on in more than one factory any change in the distribution of functions between the factories;

(4) We shall comply with the provisions of Part IX of the Drugs and Cosmetics Rules, 1945.

(5) Every drug manufactured by us for import under license into India shall as regards strength, quality and purity conform with the provisions of Chapter III of the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945;

(6) We shall comply with such further requirements, if any, as may be specified by Rules, by the Central Government under the Act and of which the licensing authority has given to the licensee not less than four months' notice.

Name of Drugs and Classes of Drugs

S. No.	Name of the Product		Specific Intended use
	Generic Name	Brand Name	

Particulars of premises where manufacture is carried on

Place: _____
Date: _____

Signature of the Manufacturer or on Behalf of the Manufacturer
(Name & Designation)
Seal / Stamp

ANNEXURE – III

TR6 Challan

T.R. - 6.
(See Rule 92)
Challan No.

Please indicate whether	Civil
	Defence
	Railways
	Posts & Telegraphs

Challan of cash paid into Treasury/Sub-Treasury .....
Bank of Baroda, K.G. Marg, New Delhi

To be filled by the remitter					To be filled by the Department Officer or the Treasury		
By whom Tendered	Name (designation) and address of the person on whose behalf money is paid	Full particular of the remittance and/of authority (If any)	Amount		Head of Account	Accounts Officer by whom adjustable	Order to the Bank
Name			Rs.	P.			
					0210-Medical and Public Health, 04-Public Health, 104-Fee and Fines	Pay and Accounts Officer Dte .GHS,New Delhi	Date Correct, Receive and grant receipt (Signature and full Designation of the Officer ordering the money to be paid in).
Signature		Total					
(in words) Rupees_____					To be used only in the case of remittance to the Bank through Departmental officer or the Treasury Officer.		
Received payment (in words) Rupees							
Treasurer	Accountant	Date			Treasury Officer Agent or Manager		

C Rules Related to Import of Notified diagnostic kits in India under Drugs and Cosmetics Act and Rules (For Information Only)

Rule-24: ***Form and manner of application for import licence.–***

(1) An application for an import licence shall be made to the licensing authority in Form 8 for drugs excluding those specified in Schedule X, and in Form 8-A for drugs specified in Schedule X, either by the manufacturer himself having a valid wholesale licence for sale or distribution of drugs under these Rules, or by the manufacturer's agent in India either having a valid licence under the Rules to manufacture for sale of a drug or having a valid wholesale licence for sale or distribution of drugs under these Rules, and shall be accompanied by a licence fee of one thousand rupees for a single drug and an additional fee at the rate of one hundred rupees for each additional drug and by an undertaking in Form 9 duly signed by or on behalf of the manufacturer:

Provided that in the case of any subsequent application made by the same importer for import licence for drugs manufactured by the same manufacturer, the fee to accompany each such application shall be one hundred rupees for each drug:

(2) Any application for import licence in Form 8 or Form 8-A, as the case may be, shall be accompanied by a copy of Registration Certificate issued in Form 41 under Rule 27-A:

Provided that in case of emergencies the licensing authority may, with the approval of the Central Government, issue an import licence in Form 10 or 10-A, as the case may be, without the issuance of Registration Certificate under Rule 27-A, for reasons to be recorded in writing.

Provided further that Registration certificate shall not be required to be accompanied with an application for an import licence under the Rules for the import of in-vitro diagnostic kits and regents, except for the diagnostic kits notified from time to time under sub-clause (iv) of clause (b) of section 3.

(3) A fee of two hundred and fifty rupees shall be paid for a duplicate copy of the licence issued under this Rule, if the original is defaced, damaged or lost.

Rule 25A: ***Condition to be satisfied before a licence in Form 10 or Form 10-A is granted.***

(1) A licence in Form 10 or in Form 10-A shall be granted by the licensing authority having regarded to:

(i) The premises, where the imported substances will be stocked, are equipped with proper storage accommodation for preserving the properties of the drugs to which the licence applies; and

(ii) The occupation, trade or business ordinarily carried out by the applicant:
Provided that the licensing authority may refuse to grant a licence in Form 10-A in respect of any applicant where he is satisfied,--

(a) That the applicant has not complied with the provisions of the Act or these rules; or

(b) That by reasons of—

(i) His conviction under the Act or these Rules or the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) or the rules made there under

(ii) Previous suspension or cancellation of the licence granted to him; he is not a fit person to whom licence shall be granted.

(2) Any person who is aggrieved by the order passed by the licensing authority under this Rule may, within thirty days of the receipt of the order, appeal to the Central Government and the Central Government may after such enquiry into the matter as it considers necessary and after giving the appellant an opportunity for making a representation in the matter, make such orders in relation thereto as it thinks fit.

Rule 26: ***Conditions of import licence: - An import licence shall be subject to the following conditions:***

(i) the manufacturer shall at all times observe the undertaking given by him or on his behalf in Form 9;

(ii) the licensee shall allow any Inspector authorised by the licensing authority in that behalf to enter with or without notice any premises where the imported substance is stocked, to inspect the means, if any, employed for testing the substance and to take samples;

(iii) the licensee shall on request furnish to the licensing authority from every batch of each substance or from such batch or batches as the licensing authority may from time to time specify a sample of such amount as the licensing authority may consider adequate for any examination required to be made, and the licensee shall, if so required, furnish full protocols of the tests, if any, which have been applied;

(iv) if the licensing authority so directs the licensee shall not sell or offer for sale any batch in respect of which a sample is or protocols are furnished under the last preceding sub-rule until a certificate authorising the sale of the batch has been issued to him by or on behalf of the licensing authority;

(v) the licensee shall, on being informed by the licensing authority that any part of any batch of the substance has been found by the licensing authority not to conform with the standards of strength, quality and purity prescribed by Chapter III of the Act, or the rules thereunder and on being directed so to do, withdraw the remainder of that batch from sale and, so far as may in the particular circumstances of the case be practicable, recall the issues already made from that batch;

(vi) the licensee shall maintain a record of all sales by him of substances for the import of which a licence is required, showing particulars of the substance and of the person to whom sold and such further particulars, if any, as the licensing authority may specify and such record shall be open to the inspection of any Inspector authorised in that behalf by the licensing authority:

Provided that in respect of the sale or distribution of drugs specified in Schedule X, the licensee shall maintain a separate record or register showing the following particulars, namely:___

1. Name of the Drug,
2. Batch number,
3. Name and address of the manufacturer,
4. Date of transaction,
5. Opening stock on the business day,
6. Quantity of drug received, if any, and the source from which received,
7. Name of the purchaser, his address and licence number,
8. Balance quantity of drug at the end of the business day,
9 Signature of the person under whose supervision the drugs have been supplied

(vii) the licensee shall comply with such further requirements, if any, applicable to the holders of import licenses, as may be specified in any Rules, subsequently made under Chapter III of the Act and of which the licensing authority has given to him not less than four months' notice.

Rule 27: ***Grant of import licence:-***

On receipt of an application for an import licence in the form and manner prescribed in Rule 24, the licensing authority shall, on being satisfied that, if granted, the conditions of the licence will be observed, issue an import licence in Form 10 [or From 10-A, as the case may be].

Rule 28: ***Duration of import licence*** –
A licence unless, it is sooner suspended or cancelled, shall be [valid for a period of three years from the date of its issue:]

Provided that if application for a fresh licence is made three months before the expiry of the existing licence the current licence shall be deemed to continue in force until orders are passed on the application.

Rule 29: ***Suspension and cancellation of import licence –***
If the manufacturer or licensee fails to comply with any of the conditions of an import licence, the licensing authority may after giving the manufacturer or licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons there for, suspend or cancel it for such period as it thinks fit, either wholly or in respect of some of the substances to which it relates:

Provided that a person, who is aggrieved by the order passed by the licensing authority under this rule may, within thirty days of the receipt of the order, appeal to the Central Government, and the Central Government may, after such enquiry into the matter as it considers necessary and after giving the appellant an opportunity for representing his views in the matter, pass such orders in relation thereto as it thinks fit.