Import/Misc./49/2019-DC
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Import & Registration Division)

Date:-
07 OCT 2019

NOTICE

Subject: Draft on Frequently asked questions for Import and Registration of drugs-regarding.

In order to streamline the regulatory process for import of drugs into India, CDSCO has prepared a draft on frequently asked questions(FAQs). Feedback/suggestion, if any, may be submitted within period of 7 days through e-mail at import.regist@cdsco.nic.in for further finalization(copy enclosed).

(Dr. S. Eswara Reddy)
Joint Drugs Controller (India)

To,

1. Indian Drug/Pharmaceutical Association Forum.

Copy to,

1. PS to Joint Secretary(R), Ministry of Health and Family Welfare,Government of India, Nirman Bhawan, New Delhi.
2. CDSCO Website

Annexure: Draft frequently asked questions(FAQs) on Import and Registration of drugs.

Central Drugs Standard Control Organisation
(Import & Registration Division)

Frequently Asked Questions on
Import and Registration of Drugs in India.

CDSCO

Government of India
Directorate General of Health Services
Ministry of Health & Family Welfare

Notice:

The replies to the FAQs are aimed only for creating public awareness about Import and Registration process by CDSCO and are not meant to be used for legal or professional purposes. The readers are advised to refer to the statutory provisions of Drugs and Cosmetics Act & Rules and respective Guidelines / Clarifications issued by CDSCO from time to time for all their professional needs.

Frequently Asked Questions on Import and registration of Drugs in India

1. **How Import of Drugs is regulated in India?**

- Import of drugs are regulated under Chapter III of Drugs & Cosmetic Act 1940 and Part IV of Drugs and Cosmetic Rules made thereunder.

2. **Which division of CDSCO (HQ) is responsible for registration/import of Drugs (for human use) in India?**

- Import and Registration Division, Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India FDA Bhawan, ITO, Kotla Road, New Delhi -110002 is responsible for registration/import of drugs in India.

3. **Which division of CDSCO (HQ) is responsible for registration/import of Drugs (for veterinary use) in India?**

- Veterinary Cell, Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India FDA Bhawan, ITO, Kotla Road, New Delhi -110002 is responsible for registration/import of drugs in India.

4. **What is Registration Certificate?**

- Registration Certificate means a certificate issued under Rule 27A of Drugs and Cosmetics Rules, 1945 by the Licensing Authority in Form 41 for registration of the premises and the drugs manufactured by the manufacturer meant for import into and use in India.

5. **What is Import license?**

- An 'import license' means either a license in Form 10 to Import of Drugs excluding those specified in Schedule X, or a license in Form 10- A to import of drugs specified in Schedule X.

6. **Who is "Manufacturer"?**

- Manufacture includes a manufacturer of drugs, who may be a Company or a unit or a body corporate or any other establishment in a country (other than India), having its drugs manufacturing facilities duly approved by the National Regulatory Authority of that country, and who also has a free sale approval of the drugs approved by the said authority in the concerned country, and/or in other major countries.

7. What are the requirements for import of Drugs in India?

- As per the Provisions under the Drugs and Cosmetics Act, 1940 and Rules thereunder Registration Certificate in Form 41 and Import License in Form 10/Form10A are required to be obtained for Import of drugs for commercial use.

8. What is the procedure for obtaining Registration certificate?

- Application for issuance of a Registration Certificate shall be made to the Licensing Authority in Form 40, either by the manufacturer himself, having a valid wholesale licence for sale or distribution of drugs under these rules, or by his authorised 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 the fee specified in sub-rule *(3)* of rule 24 A of the Drugs and Cosmetics Rules 1945 along with the information and undertakings specified in Schedules D-I and D-II duly signed by or on behalf of the manufacturer. The applicant is required to submit the application as per check list available at https://cdscoonline.gov.in/CDSCO/Industry through SUGAM online portal.

9. Whether drug manufacturing site required to be inspected before grant of Registration Certificate in Form 41? If yes, how much fees for the inspection or visit of the manufacturing premises of drugs?

- No, however if required the applicant shall be liable for the payment of a fee of USD 25000/- (or its equivalent in Indian rupees) for expenditure as may be required for inspection or visit of the manufacturing premises of the drugs.

10. What is the procedure for obtaining Import Licence?

- 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 8A 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 ten thousand rupees for a single drug and an additional fee at the rate of one thousand rupees for each additional drug and by an undertaking in Form 9 duly signed by or on behalf of the manufacturer Further, the applicant is required to submit the application as per check list available at https://cdscoonline.gov.in/CDSCO/Industry through SUGAM portal.

11. Is separate registration certificate/import License required for registration/import of more than one drug or class of drugs manufactured by a manufacturer?

- No, A single application may be made, and a single registration certificate/license may be issued, in respect of the import of more than one drug or class of drugs manufactured by the same manufacturer:

  Provided that the drugs or classes of drugs are manufactured at one factory or more than one factory functioning conjointly as a single manufacturing unit:

  Provided further that if a single manufacturer has two or more factories situated in different places manufacturing the same or different drugs a separate license/registration certificate shall be required in respect of the drugs manufactured by each such factory.

12. How to register additional drug(s) in already approved/valid Registration Certificate?

- Importer has to apply for endorsement to the existing Registration Certificate along with the requisite documents provided that the additional drug(s) is being manufactured at the same manufacturing site as stated in the Registration Certificate for each additional product 5000 USD is to be paid as a Registration fee. The requirements for endorsement of additional drug(s) to the valid Registration Certificate remain same to the fresh Registration Certificate except Site Registration Fees (10000 USD) and Plant Master File.

13. Whether separate fee is required to be paid if more than one site is involved in manufacturing of the product?

- Yes, if product is manufactured in more than one site as per activity performed such as manufacturing, primary packaging, batch release, etc separate fee is required to be paid for each site. However if all the activities are performed in the same site, fee for only one site is required to be paid.

14. What are the requirements for re-registration of drugs?

- The requirements for Re-registration of drugs remain same as that for fresh Registration requirements.

15. What is the requisite fee for application of Registration Certificate in Form 40, application for Import Licence in Form 8?

-

S.No	Legal Form	Fees
1	Form 40	USD 10000/- (or its equivalent in Indian rupees) shall be paid as registration fee for the premises meant for manufacturing of drugs intended for import into and use in India. USD 5000/- (or its equivalent in Indian rupees)

		shall be paid for the registration of a single drug meant for import into and use in India and an additional fee at the rate of USD 5000/- for each additional drug.
		USD 25000/- (or its equivalent in Indian rupees) Expenditure as may be required for inspection or visit of the manufacturing premises.
2	Form 8	INR 10000/- for a single drug and an additional fee at the rate of INR 1000/- for each additional drug.

Note:- Additional fee of USD 10000/- shall be paid if primary packing site, testing site, batch release site are different from main manufacturing site.

16. What is the procedure for payment of fee ?

- The fees shall be paid through Non Tax receipt portal i.e. www.bharathkosh.gov.in under the details mentioned below

Grant	Head of Account	Description of Non Tax Receipt	Name of DDO
900	0210-04-1040000-00-1	Fees & Fines (Clinical Trials, Import and Registration, New Drug	CDSCO (HQ), New Delhi

17. What is the timeline for grant of Registration Certificate?

- If the application is complete in all respects and information specified in Schedules D-I and D-II are in order, the Licensing Authority shall, within nine months from the date of receipt of an application, issue such Registration Certificate in From 41.

18. What is the duration/validity of "Registration certificate" in Form-41 for Import of Drugs in India?

- A Registration Certificate, 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 the application for a fresh Registration Certificate is made nine months before the expiry of the existing certificate, the current Registration Certificate shall be deemed to continue in force until orders are passed on the application

19. What is the duration/validity of "Import License" in Form-10 for drugs in India?

- A Import License unless, it is sooner suspended or cancelled, shall be valid from the date of its approval till the validity of registration certificate for that product.
- 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.

20. Whether drugs having valid Import License, can be imported from any notified ports of India?

- Yes.

21. Whether multiple Import Licenses are required for drugs that are registered under one Registration Certificate by the same Indian Agent/ importer in case he wants to import from different notified ports?

- No, Single license may be issued, in respect of the import of more than one drug or class of drugs manufactured by the same manufacturer to the Importer through which importer can import the products through any notified port under Drugs and Cosmetics Act and Rules.

22. Whether drugs imported under valid import License can be stocked in any other wholesale license premises other than stated in the Import License?

- Yes.

23. What is the time period for Grant of Import license?

- If the application is complete in all respects and information provided are in order, the licensing authority may within forty five days from the date of receipt of an application, issue an import license in Form 10.

24. Whether the importer/ Indian agent is required to obtain approval for Post Approval Change before applying for renewal RC ?

- Yes, the applicant should obtain Post Approval Changes before filing for re-registration so that the Post approval Change be reflected in renewal RC.

25. If applicant has applied for Registration Certificate and still not issued but in between there is the change has happened in the constitution of either Manufacturer or Indian Agent, address of manufacturer whether fresh fees is required for plant registration and product registration?

- Yes. The applicant has to submit the fresh application including fee.

26. Is it possible for an applicant to submit their applications for Registration Certificate (Form 41) and Import License (Form 10) together?

- Before applying for Import License, the firm is required to obtain RC, Once the site gets registered then only Import License can be applied.

27. Whether simultaneous application can be made for new drug approval and registration Certificate?

- In case of New drugs the applicant can apply simultaneously for New Drug approval and Registration Certificate However the RC will be issued only after the grant of New Drug Permission.

28. If applicant wants to apply for Registration Certificate but the product is not sold in the country of origin but is registered and marketed in any one of the following countries i.e. USA, Europe, Japan, Health Canada or Australia. Can he apply for Registration Certificate?

- Yes.

29. If the drug regulatory body in country of origin is not issuing free sale for active pharmaceutical ingredients (API)/finished formulation then what equivalent document to be submitted?

- A duly notarized copy of Certificate of Pharmaceutical Products (COPP) is required to be submitted and certificate should mention that the drug substance is marketed in the exporting country from any other country.

30. If GMP certificate for API as per WHO GMP is not available then what is equivalent certificate to be submitted?

- It is preferred to submit GMP certificate as per WHO GMP, however written confirmation for active substances exported to European Union issued by National Regulatory Authority of country of origin or a duly notarized copy of the certificate equivalent to GMP certificate as per WHO GMP guidelines issued by United States of America or Japan or Australia or Canada or European Union for the purpose of marketing of the drug in their country can be submitted.

31. Whether apostilled POA can be accepted in place of power of attorney executed and authenticated either in India before a First Class Magistrate, or in the country of origin before such an equivalent authority, the certificate of which is attested by the Indian?

- Yes, apostilled POA can be accepted.

32. Can Import License without registration certificate be obtained?

- As per Sub rule (2) of Rule 24, In case of emergencies the Licensing Authority may, with the approval of the Central Government, issue an import license in Form 10 or 10A, as the case may be, without the issuance of Registration Certificate under Rule 27A, for reasons to be recorded in writing.

33. Whether Registration certificate/Import license is required for inactive bulk substance to be used for a drug formulation, with or without pharmacopoeial conformity?

- Registration Certificate/Import Licence is not required under the Drugs and Cosmetics Rules in respect of an inactive bulk substance to be used for a drug formulation, with or without pharmacopoeial conformity.

34. Whether acquisition/merger of registered manufacturer by another company is considered as change in constitution of the company?

- Yes.

35. Whether any change in Indian agent requires approval from Licensing Authority?

- Yes, Indian agent requires to intimate the licensing authority under relevant categories of Post approval change applications under SUGAM and obtain Post Approval Change.

36. What is Form 9 ?

- It is an undertaking, to accompany an application for an import license, issued by Manufacture/Authorised Indian agent.

37. What is the labelling requirement for Import of drugs?

- As per Rule 32 of Drug and Cosmetic rules 1945, no drug shall be imported unless it is packed and labelled in conformity with Parts IX and X of Drugs and Cosmetics, Rules, 1945.

38. What are mandatory addresses on the labels of registered drugs being Imported/ marketed in India as per the Drugs and Cosmetics Act, 1940?

- Name and address of Legal Manufacturer/Actual manufacturer and importer as stated in Form-10.

39. Whether registration certificate and import license are required for the drugs transit through India to foreign Countries and which is not required to be sold or distribution in India?

- Registration certificate and Import license are not required for the drugs transit through India to foreign Countries and which are not required to be sold or distributed in India.

40. What standards to be complied with imported drugs?

- The imported drugs shall comply with standards prescribed under the Second Schedule of Drugs and Cosmetics Act, 1940.

41. What standards to be complied for the drugs not included in the Indian Pharmacopoeia but which are included in the Official Pharmacopoeia of any other country?

- Standards of identity, purity and strength specified for drugs in the edition of such official Pharmacopoeia of any other country for the time being in force and such other standards as may be prescribed.
- In case the standards of identity, purity and strength for drugs are not specified in the edition of such official Pharmacopoeia for the time being in force, but are specified in the edition immediately preceding, the standards of identity, purity and strength shall be those occurring in such immediately preceding of such official Pharmacopoeia and such other standards as may be prescribed.

42. Whether is it mandatory to mention letters I.P on the label of the Imported Drug?

- Yes. The letters I.P. and recognized abbreviations of pharmacopoeias and official compendia of drug standards prescribed under these Rules shall be mentioned on the label of the drug only for the purpose of indicating that the drug is in accordance with standards set out in the Indian Pharmacopoeia or in any such pharmacopoeia or official compendium of drug standards recognized under the Rules.

43. What are the different categories of Post approval changes?

- Different categories of Post approval changes are available under https://cdscoonline.gov.in/CDSCO/Industry.

44. Can a post approval amendment under RC no.X be filed in parallel with application for RC renewal/endorsement in the same RC no. X ?

- It is advisable to initially get approval for post approval amendment before applying for RC renewal or Endorsement, otherwise the Post Approval change will not be reflected in the renewed RC/endorsment.

45. What is meant by non-medical use?

- As per Schedule D of the Drugs and Cosmetic Rules, 1945, if the substance is imported in bulk, the importer shall certify that the substance is imported for non-medical uses, and if imported otherwise than in bulk, each container shall bear label indicating that the substance is not intended for medicinal use or is intended for some purpose other than medicinal use or is of commercial quality. [Further, permission from Licensing Authority as defined in clause (b) of rule 21 has to be

obtained for import of the substance for non-medicinal use without registration and import licence.]

46. Where to approach for obtaining dual use NOC?

- Applicant is required to apply to concerned Zonal offices of CDSCO for grant of dual use NOC.

47. Whether RC is required for import of drugs for not intended for medical use?

- As per Rule 43 of Drugs and Cosmetics Rules 1945, import of drugs not intended for medical use are exempted from provisions of Chapter III of the Act and rules thereunder to the extent, and subject to the conditions specified in Schedule D.

48. Whether Import License and Registration Certificate is required for intermediates having no therapeutic value like 6-Amino Pencillinic Acid (6-APA)?

- As the product 6-AFA is an intermediate for manufacturing of amoxicilian trihydrate etc, therefore, no registration certificate/Import Licence under the provisions of Drugs and Cosmetics Act 1940 and Rules 1945 is required.

49. How drugs under Charity purpose are imported in country?

- As per Rule 36A of Drugs and Cosmetics Rules 1945 for Import of Drugs by charitable hospitals free of cost which states that "Small quantity of drugs received in donation by a charitable hospital for the purpose of treatment of the patients in the said hospital may be imported provided the drugs are given or administered to the patients free of cost".
- "The drugs shall not be prohibited for import and permitted to be marketed in the country with residual shelf life of one year or more."

50. Can unapproved/banned drug can be imported for charity purpose?

- No.

51. How a drug with shelf life less than 60% be imported?

- As per Rule-31 of Drugs &Cosmetics Rules 1945, "No drug shall be Imported unless it complies with the standard of strength, quality and purity, if any", provided thereunder that the Licensing Authority shall not allow the import of any drug having less than sixty percent residual shelf life period as on the date of import. Provided also that, in exceptional cases the Licensing Authority for reasons to be recorded in writing, may allow, the import of any drug having lesser shelf-life period, but before the date of expiry as declared on the container of the drug. For obtaining such import permissions, the importers are required to submit their application to CDSCO (HQ).

52. What is the provision for import of drugs for manufacture and export by units situated in "Special Economic Zones" as notified by the Government of India?

- As per Schedule D of Drug and Cosmetic rules 1945, import of drugs for manufacture and export by units situated in "Special Economic Zones" as notified by the Government of India are exempted from provisions of Chapter III of the Act and rules thereunder which required them to be covered by an import licence, import registration and import through notified port of entry, subject to the conditions that these drugs shall not be diverted for sale in the country.
- Provided that such imported drugs may be permitted to domestic area if they meet the requirements of standard procedure for import and registration as required under Chapter III of Act and rules thereunder.

53. What is the procedure for obtaining approval in case of change in name of Indian Agent?

- Initially, the firm is required to obtain approval through SUGAM online portal for change in name of Indian agent which was earlier registered. Thereafter, for change in name of Indian agent in License/ Approvals, firm is required to apply to respective division of CDSCO through SUGAM online portal, for obtaining fresh 'RC''with fresh validity.It is further advised that the applicant shall clearly mention all the details related to the changes, NOC obtained etc. in the covering letter for better clarity.

54. What is the fee required for obtaining amendment in Registration Certificate?

- Revised Fees as per G.S.R. 1193 (E) dated 12/12/2018 in post approval amendment/Changes in RC is as

S. No	Type of amendment	Fees
1	Change in foreign manufacturer address in RC (No Location change)	USD 1800/-
2	Change of Shelf-life in RC(Extension)	USD 1800/-
3	Change of Shelf-life in RC(Reduction)	USD 1800/-
4	Change in address of registered manufacturer in RC (No Location change)	USD 1800/-
5	Change in Manufacturing process, or in packing, or in labeling, or in testing or in documentation of any of drug pertain to RC (Minor/Major)	No fee is required for minor change. However, fee of USD 5000 per product to be submitted for a major change/modification in manufacturing process or in packing or in labeling or in testing or in documentation as the case may be, at the

		discretion of the Licensing Authority.
6	Change of name of manufacturer in RC without constitution change	USD 1800/-
7	Change of Pharmacopoeial specification in RC	USD 1800/-
8	Change of Pharmacopoeial specification of drug ingredients in FF in RC	USD 1800/-
9	Deletion of site involved in manufacturing of drugs	USD 1800/-

Note:-

I) Foreign manufacturer means the manufacturing site which is to be registered in Registration Certificate.

II) Registered manufacturer means the address of the firm used for communication purpose, such as corporate office address or it may be same as that of foreign manufacturer.

55. In which cases fresh RC is required to be obtained under the provisions of the Drugs and Cosmetics Rules?

- As per the condition no. 6 of the Registration Certificate in Form 41 under the provision of the Drugs and Cosmetics Rules *"the manufacturer or his authorised agent in India shall inform the Licensing Authority immediately in writing in the event of any change in the constitution of the firm and /or address of the registered office/ factory premises operating under this Registration Certificate. Where any such change in the constitution of the firm and/or address takes place, the current Registration Certificate shall be deemed to be valid for a maximum period of three months from the date on which the change has taken place unless, in the meantime, a fresh Registration Certificate has been taken from the Licensing Authority in the name of the firm with the changed constitution of the firm and/or changed address of the registered office or factory premises."*

Accordingly, firm is required to obtain a fresh Registration Certificate under the provision of the Drugs and Cosmetics Act, 1940 and the Rules in the following cases:-

- Change of name of foreign manufacturer or registered manufacturer in RC with constitution change.
- Change of Indian Agent in RC with Constitution change.
- Change in foreign manufacturer address in RC with location Change.
- Change of address of Indian Agent in RC with location change.

- Change in address of registered manufacturer in RC location change.
- Change in constitution of manufacturer.

56. What is the procedure for obtaining Registration Certificate for Change in Indian Agent with constitution and/or change in address?

➢ Manufacturer or his authorised Indian agent shall inform the licensing authority immediately in writing in the event of any change in constitution of firm and/or address of registered office/factory premises operating under Registration Certificate. Where any such change in the constitution of the firm and/or address takes place, the current Registration Certificate shall be deemed to be valid for a maximum period of three months from the date on which the change has taken place unless, in the meantime a fresh registration certificate to be taken.

57. In which cases amendment of Registration Certificate, fee is required to be paid?

➢ As per GSR 1193, a fee of 1800USD is required to be paid if an amendment in RC involves amendments such as amendment is Pharmacopeial status, shelf life, sale pack (presentation), storage condition, deletion of site, amendment in Change in address of registered manufacturer in RC (No Location change), Change of name of manufacturer in RC without constitution change, Change of Pharmacopoeial specification in RC, Change of Pharmacopoeial specification of drug ingredients in FF in RC, Deletion of site involved in manufacturing of drugs, replacement/addition/deletion of source of diluant such as water for injection etc.

58. In which cases of amendment of RC, fee is not required to be paid?

➢ In changes such as Change in batch size of finished product, tightening of test limits to existing tests, inclusion of warning and precautions in package insert or any editorial changes, change of source Excipients /API in finished formulation etc can be considered as 'minor' change and fee will not be required to be paid.

59. In which cases of major change/modification in manufacturing, or in processing, testing, or in documentation, a fee of 5000USD to be paid?

➢ As per the condition no.5 of Form 41, where there is any major change/modification in manufacturing, or in processing, testing, or in documentation as the case may be , at the discretion of the Licensing Authority, the manufacturer or his authorized agent in India shall obtain necessary approval within 30 days by submitting a separate application along with the registration fee, as specified in clause (ii) of sub rule(3) of rule 24-A, however for guidance of stakeholders following examples can be used to assess the major change/modification.

S.No	Change	Example
1.	Change/modification in manufacturing/ process	i) The manufacturer was manufacturing the tablet dosage

		form with wet granulation method and now the process of manufacturing has been modified to direct compression method. ii) Modification in packing packaging system such as change in packaging from aluminium foil to Alu-Alu etc. iii) Change in liquid form of injection to lyophilized form etc.
2.	Change/modification in testing	i) Initially the testing was conducted by HPLC method However, subsequently changed to Gas Chromatography /Microbiological method etc.
3	Change/Modification in documentation	i) Change in Indication of the drug or addition of indication to existing approved indication.

Note:- However all the changes should have been approved in country of origin and in case of New drug, Form 45 to be obtained.

60. What is ICEGATE ?

- ICEGATE stands for the Indian Customs Electronic Commerce/Electronic Data interchange (EC/EDI) Gateway. ICEGATE is a portal that provides e-filing services to the trade and cargo carriers and other clients of Customs Department (collectively called Trading Partner).

61. What is e-SANCHIT ?

- e- SANCHIT is e-Storage and Computerized Handling of Indirect Tax documents for paperless processing, uploading of supporting documents, to facilitate the trading across Borders.

62. Who can login e-SANCHIT?

- Only ICEGATE registered users can use e-SANCHIT by accessing the e-SANCHIT link.

63. What is IRN & DRN?

- DRN stands for Document reference number, which is the unique reference to a batch of uploaded documents. IRN stands for Image reference number, which is unique to each document. A group of IRN should be entered into the Bill of Entry, not DRN.

64. If validity of RC is expired, what is the procedure for obtaining the Registration Certificate?

- In such cases, the applicant shall apply for fresh registration as per check list provided under https://cdscoonline.gov.in/CDSCO/Industry.

65. Whether AERB approval is required for Import and Registration Certificate of Radiopharmaceuticals?

- No Objection Certificate issued by Atomic Energy Regulatory Board is a prerequisite before applying for Import and Registration Certificate of radiopharmaceuticals.

66. Whether the timelines calculated by CDSCO includes the times taken by the applicant to reply to queries?

- Timelines start from the date of submission of application at CDSCO. However, the timeline does not include the time taken by the applicant to reply the queries.

Feedback/Suggestions, if any, in this regard, may be submitted to :

Central Drugs Standard Control Organization, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India FDA Bhawan, ITO, Kotla Road, New Delhi -110002 Email: import.regist@cdsco.nic.in