

**Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization**

Notice

File No.: IT-13011(11)/1/2023-eoffice

Date: 01/01/2024

Subject – Launching of National Single Window System (NSWS) Portal- reg.

NSWS is established by the Central Government with the objective to build a genuine Single Window System which act as a one-stop shop for all the approvals required by the investor and facilitates ease of doing business. The scope of NSWS includes all the approvals/licenses/registrations/clearances as applicable.

In this regard, Invest India through TCS has developed NSWS portal has been developed for CDSCO, which will be independent from the existing SUGAM portal or cdscomonline portal. Initially following three activities under the Medical Devices Rules, 2017 have been developed and will be made 'Live' on NSWS portal w.e.f. 01.01.2024:-

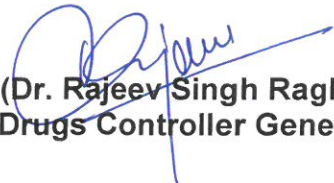
1. Application for grant of Certificate of Registration of a Notified Body-Form MD-01.
2. Application for licence to manufacture medical device for purpose of clinical investigations, test, evaluation, examination, demonstration or training-Form MD-12.
3. Application for Licence to Import Medical Devices for the Purposes of Clinical Investigations or Test or Evaluation or Demonstration or Training -Form MD-16.

In view of above, it is requested that all concerned stakeholders henceforth should submit application related to above said three activities through NSWS portal only and the existing cdscomonline portal for the said activities will be disabled **w.e.f. 15.01.2024.**

The NSWS portal can be browsed through <https://www.nsws.gov.in> and a user guide is also attached herewith for guidance for ready reference.

This is for information of all concerned stakeholders.

Encl.: As above


**(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)**

To:

1. All the concerned stakeholders
2. CDSCO Website

National Single Window System

User Guide:

How to apply for CDSCO Approval

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How to view, add approval through Central KYA

उद्योग संकल्प और आंतरिक व्यापार विभाग
DEPARTMENT FOR PROMOTION OF INDUSTRY AND INTERNAL TRADE

INVEST INDIA

About FAQs Guide Contact ENG

National Single Window System

CENTRAL APPROVALS
Issued by Ministries of Govt. of India

STATE APPROVALS
Issued by States of Govt. of India

GOVERNMENT SCHEMES
Avail the benefits by Govt. of India

LOGIN

Access over **612 Central Approvals** and **4197 State Approvals**

Explore, Apply and Get all the approvals required to start your business in India

Central Approvals Search Approvals EXPLORE ALL

Don't know which approvals are required? [Click Here & Know Your Approvals](#)

"We are laying a red carpet for all global companies to come and establish their presence in India. Very few countries will offer the kind of opportunities India does today."

Hon'ble Prime Minister Narendra Modi

Click on 'Know Your Approvals' on the NSWS homepage

National Single Window System

Begin your journey through KYA which helps generate a list of Centre and State approvals that may be required to start your business operations in India. This list of approvals is for guidance purposes only.

Which one would you like to go with first?

Central State

Continue with Central Back to Homepage

You understand that the 'Know Your Approval' feature is completely dependent on the information provided by You and is only indicative in nature to identify a list of Approvals and Registrations that may be required for Your business. This list does not constitute a legal opinion or advice and should be used only for reference purposes. We recommend you to undertake your own independent analysis and ensure that your application falls under the respective Ministry/ Department's

Click on 'Continue with Central' to open the central KYA



How to view, add approval through Central KYA

Click on 'Business Activity Details'

STEP 1 Business Registration

STEP 2 Business Activity Details

STEP 3 Foreign Investment Details

STEP 4 Project Land Details

Additional information

Would you like to provide any of the following services / establish facilities?

Which sector(s) best describes your project/ business activity?

Healthcare

Agriculture, Sericulture and Forestry

Aviation

Banking and Financial Services

Defence Manufacturing

Healthcare

Education and Skill Development including Medical Institutions

Food & Beverages, Catering, including Animal Husbandry and Fisheries

Infrastructure

Leather & Textiles

Select "Healthcare" and Answer the questionnaire and find applicability of different approvals to you

Click here to read more information

Know Your Approvals - Central

My Approvals (1)

STEP 1 Business Registration

STEP 2 Business Activity Details

STEP 3 Foreign Investment Details

STEP 4 Project Land Details

Will your business activity require dealing in chemicals? (Toxic, Hazardous, Petrochemicals, Chemicals & Fertilizers)

Yes No

Please select all products/services applicable to your business which you would additionally like to apply for:

Select

Submit to Know Your Approvals

Save as Draft

Reset Form

Click on 'My Approvals' tab to view the list of added approvals

Click 'Submit to Know Your Approvals' to view the list of approvals

To save a draft of the KYA answers, users must be logged into NSWS

Click on 'Reset form' to remove all previous responses to the questions



How to add identified approval to the Dashboard

उद्योग संवर्धन और आंतरिक व्यापार विभाग
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National Single Window System

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LOGIN

My Approvals(4) Edit KYA

Based on the information provided by you in the previous step, below is the list of approvals identified. This list of approvals is for guidance purposes only and does not constitute legal and/or official advice.

CENTRAL APPROVALS (4)

- 1 Form CT-10 Application for grant of permission for bioavailability or bioequivalence study or for examination, test and analysis
For Business Activity Details • Issued by Directorate General of Health Services • Ministry of Health and Family Welfare
- 2 CT-13 Application for grant of permission to manufacture unapproved active pharmaceutical ingredient for development of formulation for test or analysis or clinical trial or bioavailability or bioequivalence study
For Business Activity Details • Issued by Directorate General of Health Services • Ministry of Health and Family Welfare
- 3 MOH_Permission to manufacture new active pharmaceutical ingredient for development of formulation for test or analysis or clinical trial or bioavailability or bioequivalence study
For Business Activity Details • Issued by Directorate General of Health Services • Ministry of Health and Family Welfare
- 4 MOH_Licence to manufacture drugs for purposes of examination, test or analysis
For Business Activity Details • Issued by Directorate General of Health Services • Ministry of Health and Family Welfare

To add the list of approvals on the Dashboard, log into NSWS

Add to Dashboard

Know State Approvals

Save PDF

Save the existing list of approvals in pdf format using 'Save PDF'

National Single Window System

Sign In

To access your dashboard and apply for approvals.

Email Address

Password

Sign In

Don't have an account? [Sign Up Now](#)

We have

28 Ministries 22 States

Ministry of Civil Aviation Government of India

Ministry of Labour and Employment Government of India

Ministry of Corporate Affairs Government of India

Ministry of Information and Broadcasting Government of India

Ministry of Communications Government of India

Ministry of Fisheries, Animal Husbandry, and Dairying Government of India

Ministry of Finance Government of India

Ministry of Education Government of India

Government of Andhra Pradesh

Government of Arunachal Pradesh

Government of Bihar

Government of Gujarat

Government of Karnataka

Government of Goa

Users will be redirected to the 'Sign In' Page

Existing users can 'Sign In' with their credentials

New users can create an account using 'Sign Up Now'

How to login and apply for approval (New User)

Sign Up
We're so happy you're here, let's start by signing up.

Full Name*
Mukul Kumar

Email*
mukul123@gmail.com [Verify](#)

Mobile Number*
+91 9999999999 [Verify](#)

Set Password*
.....

Sign Up Now

By creating an account, I accept the Terms & Conditions and Privacy Policy

Have an account? [Sign In](#)

We have
28 Ministries 22 States

New users can create their login credentials. Add their Email ID & Phone Number and verify both of them

Click on 'Sign Up Now'

Welcome
Mukul Kumar!
You have been successfully registered on NSWS

2/4

Setup your profile
Select your legal entity type

Select the applicable option

INCORPORATED COMPANY
Select if you have a CIN

LIMITED LIABILITY PARTNERSHIP
Select if you have an LLPIN

SOLE PROPRIETOR

OTHERS

NONE OF THESE, I'M PLANNING TO REGISTER A NEW ENTITY

NONE OF THESE, FDI IN INDIA

Enter CIN

NEXT

Enter the CIN / LLPIN / Business Name and click on 'Next'



How to fill the application form

ERNST AND YOUNG INDIA PRIVATE LIMITED
Incorporated on - 24/07/2002 CIN - U74140DL2002PTC116314

My Dashboard My Documents Members Profile

My Dashboard
Manage and track the status of your application

Central Approvals in List (2 approvals)

Approval Name	Applied on	Last Submitted By	Assigned to	Application Status	Application fees	Action
FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS + New Application	-	Mukul Kumar	Ministry of Health and Family Welfare	Not Applied	Subjective*	Apply Now
MDH_Permission to conduct clinical performance evaluation of new in vitro diagnostic medical device	-	Mukul Kumar	Ministry of Health and Family Welfare	Not Applied	₹ 25000	Apply Now

← Go Back

Fill Application Form

Submit all the mandatory details(*) in the application form to apply

FILL FORM REVIEW FORM MAKE PAYMENT

FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS

Part A
FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, ...

2

Pre Registration Form

Applicant Address Details

Test or Analysis Site

Foreign Manufacturer details

+ Expand All



How to fill the application form

National Single Window System

 CENTRAL APPROVALS
Issued by Ministries of Govt. of India

 STATE APPROVALS
Issued by States of Govt. of India

 GOVERNMENT SCHEMES
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 MY DASHBOARD

Pre Registration Form

Select Department * Biological - Blood Products

CDSO Applicable zone/HQ * ▼

I agree that I will provide accurate information and I will be solely responsible for any false or inaccurate information provided to the division. *

Applicant Address Details

Name of the Applicant * Mukul

City *

Product Details

For each strength make new section application

Type of Drug *
 Bulk Drug Finished Formulation

Name of Drug/Formulation *

Class of Drug * Select ▼

Quantity

Quantity
Unit *
Select ▼

+ Add Section

Product Details 2

For each strength make new section application

Type of Drug *
 Bulk Drug Finished Formulation

Name of Drug/Formulation *

Class of Drug *



How to fill the application form

BA/BE Study Details

Comparator Drug Details

Comparator Drug Name *

Name of Company

Name of Country *

+ Add Group ← This button will create a duplicate group for the selected group

Comparator Drug Details 2

Comparator Drug Name *

Name of Company

Name of Country *

Foreign Manufacturer details

Name of the Foreign Manufacturer *

Country *

Address Line 1 *

Address Line 2 *

State/Province/Region *

City *

Zip/Postal code *

Fax No *

Landline No *

Please include Country Code - State Code - Landline Number

Click on '(i)' icon to read Additional Information



How to fill the application form

<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No
An explanation about whom to contact for trial related queries, ri	The anticipated prorated payment, if any, to the Subject for partic
<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No
Subject's responsibilities on participation in the trial	Statement that participation is voluntary, that the Subject can wit
<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No
PI's undertaking	International prescribing information
<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No
Justification ⓘ	
<input type="text"/>	

Use this button to save the progress of the filled up application

Move to the Checklist form for uploading the required documents

Checklist

1. Name of Applicant (Applicant Details)

Name of Applicant (Applicant Details) *

Select Document type and Click on 'Browse File' to add attachments

Supported files are PDF

Name of Applicant (Applicant Details) - Remarks *

2. Drug Details

Drug Details *

This button indicates that the user needs to Download a format, fill it up and upload the same on that particular field

Supported files are PDF

Drug Details - Remarks *



How to fill the application form

The screenshot shows the 'National Single Window System' interface. At the top, there are navigation tabs for 'CENTRAL APPROVALS', 'STATE APPROVALS', and 'GOVERNMENT SCHEMES'. The main content area contains a text box with a disclaimer: 'An undertaking that the device in question conforms to the requirements of these rules, apart from aspects covered by evaluation and apart from those specifically itemised in the undertaking, and that every precaution has been taken to protect the health and safety of the patient, user and other persons'. Below this, there are two file upload sections. Each section has a 'Browse File' button, a list of supported files (PDF, dummy.pdf), and a 'Remarks' field. The first section has 'Document' in the remarks field, and the second has 'Uploaded'. At the bottom, there is a 'Review & Submit' button and a callout box with an arrow pointing to it, containing the text: 'Once filled, click on Review and Submit'.

The screenshot shows the 'National Single Window System' interface for 'FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS'. A progress bar at the top indicates the current step is 'REVIEW FORM'. The form is divided into 'Part A' and 'Part B'. 'Part A' includes a table for 'Pre Registration Form' with the following details:

Select Department	Biological - Blood Products
Purpose of Application	For Examination, Test or Analysis
CDSO Applicable zone/HQ	CDSO HQ
I agree that I will provide accurate information and I will be solely responsible for any false or inaccurate information provided to the division.	Accepted

Below the table, there is a section for 'Applicant Address Details'. To the right of the form, an 'Application Fee' of ₹5,000 is displayed. A callout box with an arrow points to this fee, containing the text: 'Applicable fee will be visible here'. At the bottom, there is a checkbox with the text: 'I have reviewed all the information provided by me and confirm that it is correct to the best of my knowledge.' To the right of this checkbox are two buttons: 'Pay @ Submit' and 'Back to edit details'. A callout box with an arrow points to the 'Pay @ Submit' button, containing the text: 'Review the application and click here for final submission'.



How to fill the application form

Review your application
Please carefully review the application before submission

FORM-12- APPLICATION

Part A
FORM-12- APPLICATION TO IMPORT DRUGS

Disclaimer

By proceeding with the payment, You acknowledge that the payment is being made directly to the concerned Ministry towards application fees (if applicable) or any other fees that may be charged by them. NSWS shall not be obligated to pay or refund any monies to You in any circumstance and is also not liable to facilitate refund of any payment made by You to the concerned Ministry. You may reach out directly to the concerned Ministry/ State in case of any discrepancies.

I have read and accept.

Pay & Submit **Cancel**

Click on the checkbox and then "Pay & Submit" button

training.pfms.gov.in/Bharatkosh/NTRP/Home/Confirmation

Pay the amount using the Bharatkosh portal

Non-Tax Receipt Portal

1 Payment Purpose 2 Depositor's Details 3 Confirm Info 4 Pay

Payment Mode Online

Depositor's Details

Name	MUKUL KUMAR		
Address 1	DS50	Address 2	
City	WEST DELHI	District	
State	DELHI	Country	INDIA
Pincode/Zipcode	110063	Email	mukul682937@gmail.com
Mobile No. (+91)	7042517135		
TAN		TIN	

Purpose Details

Sr. No.	Ministry	P&O Name	DDO Name	Purpose and Payment Type	Payment Period / Frequency	Amount (in INR)
1	HEALTH and FAMILY WELFARE	PAO(DGHS), New Delhi(020946)	Section Officer, CDSCO (HQ), New Delhi(203700)	Import and Registration,	One Time	5000
				INR five thousand only		Total:5000

Back **Confirm**

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How to fill the application form

3 easy steps to add Digital Signature

- Step 1: Download and run emBridge Application. [Download](#)
- Step 2: Insert your crypto-token Pen Drive into system
- Step 3: Fill details here to add digital signature

After payment, user will be redirected to NSWS portal where the user has to Digitally Sign the application

Document for sign: MOH_Certificate for Registration

This is the document containing the responses of the investor in the application with their DSC. Also known as Legal Form

Provider: Microsoft Windows Store
Certificate: Class 3 Individual Test
Token Password: ****

Sign & Submit

Submitted Successfully

Your application for 'MOH_Certificate for Registration of Notified Body' has been submitted successfully to the respective Ministry. Please check the status from your dashboard.

Application ID: SW/MD/MD-1/2023/00000300

Application ID	SW/MD/MD-1/2023/00000300
Paid Amount	₹25000
Transaction ID	T1687768381684A53704L3335P22603
Date	26 Jun 2023 02:03 pm
Email	muskan3675@gmail.com

Done

This screen confirms the submission of application



How to fill the application form

My Dashboard
Manage and track the status of your application

1 My Central Approvals | 0 My State Approvals

Central Approvals in List (1 approvals)

0 Not Applied | 1 Submitted To Ministry | 0 Assigned To Me | 0 Approved | 0 Rejected

Search by Approval Name | Add More Approvals

Approval Name	Applied on	Last Submitted By	Assigned to	Application Status	Application fees	Action
MNH_Cert...				Submitted	₹ 25000	Upload Doc. ...

Once submitted, user can track the 'Application Status' from here

In case the user wants to submit any additional document. They can click here

5. Additional Documents :

Document Type *
1.2 Organization profile of notified body including organogram, busin...

Upload document *
[other] Browse File

Supported files are PDF

Remarks *

+ Add Section

Review & Submit | Save as Draft

Upload the documents, add the information

Click on review and submit, and verify the application again using DSC as shown earlier



How to view the application form (Legal Form)

The screenshot shows the National Single Window System dashboard. At the top, there are navigation links for 'About', 'FAQs', 'Guide', and 'Contact', along with a language selector set to 'ENG'. Below this, there are sections for 'National Single Window System', 'CENTRAL APPROVALS', 'STATE APPROVALS', and 'GOVERNMENT SCHEMES'. A 'MY DASHBOARD' button is visible in the top right. The main content area shows an application for 'MOH_Certi' with a status of 'Submitted'. There are buttons for 'Go Back', 'Save PDF', and 'Approval Details'. A callout box with an arrow points to the 'Download Digitally Signed Application' button, stating: 'In Case the user wishes to see the Legal form they can do so by clicking on this button'. Below the application details, there are tabs for 'Form 1', 'Form 2', 'Document', and 'Payment'. The 'Form 1' tab is active, showing the title 'Form 1 - MD-1 Application for grant of Certificate of Registration of a Notified Body'. On the right, 'Processing Details' show the application was submitted on 26/06/2023 at 2:18 pm by 'Muskan...'. The application ID is SW/MD/MD-1/2023/00000300.

The screenshot shows the 'Form MD-1' application form. The title is 'Form MD-1 (See sub-rule (5) of rule 13) APPLICATION FOR ISSUE OF CERTIFICATE OF REGISTRATION OF NOTIFIED BODY'. The form contains the following fields:

- 1. Name Of Applicant : -
- 2. Nature and Constitution of Body : Proprietorship
- 3. Corporate/Registered Office Address : KRISHNA NAGAR , North Delhi, Delhi, 110051 (India), -, 5756765
- 4. Details of accreditation :
 - Issued by : NABCB
 - Issued On : 06/01/2023
 - Valid Upto : 06/28/2023
- 5. Standard for which notified body has been accredited under rule 13 : ISO 13485
- 6. Payment Fees Details : Refer details in Payment Receipt.
- 7. Documents enclosed as specified in the Part 1 of the Third Schedule of the Medical Devices Rules, 2017, duly signed by me.

At the bottom, there is a declaration: 'I/We undertake to comply with the provisions of the Drug and Cosmetic Act, 1940(23 of 1940) and the Medical Device Rules, 2017 and other terms and conditions for working as a Notified Body as may be specified from time to time'. The form also includes fields for 'Place : delhi', 'Date : 26/06/2023', 'Name : Shaik Gajula', and 'Designation : owner'. A signature line is present at the bottom right.

A callout box on the left side of the form states: 'The legal form can be previewed/downloaded'.



Checklist Activation

[← Go Back](#)

Fill Application Form

User will be presented with multiple tabs containing different checklists. Only one Checklist will be enabled for the investor to fill up, based on their Responses in the Pre Registration Form

Form CT-12 - Application for grant of permission to manufacture formulation of unapproved active pharmaceutical ingredient for test or analysis or clinical trial or...

Form 1
Form CT-12 - Application for grant of permission to manufacture formulation of un...

Pre Registration form

Select Department *
Select

Purpose of the application: *
Select

Location for processing of application *
Select

I agree that I will provide accurate information and I will be solely responsible for any false or inaccurate information provided to the division. *

National Single Window System

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MY DASHBOARD

FILL FORM REVIEW FORM MAKE PAYMENT

[+ Expand All](#)

Form CT-12 - Application for grant of permission to manufacture formulation of unapproved active pharmaceutical ingredient for test or analysis or clinical trial or...

Form 1
Form CT-12 - Application for grant of permission to manufacture formulation of un...

Pre Registration form

Select Department *
Biological (r-DNA incl Re combinant Blood Product)

Purpose of the application: *
Clinical Trial

Location for processing of application *
CDSCO Head Quarter

Applicable HQ *
HQ - Biological (r-DNA incl Re combinant Blood Product)

I agree that I will provide accurate information and I will be solely responsible for any false or inaccurate information provided to the division. *

Application Details

Fill up the details on Pre registration Form. Click on the checkbox. Post this, Once the user clicks on Next Form at the bottom of the page, user will be presented with the checklist they have to fill.



Checklist Activation

Form 9
CT12-BIO-rDNA-FFBD-Clinical Trial-Checklist

Checklist

1. Covering Letter

1. Covering Letter *

CDSO Checklist

Supported files are PDF
dummy.pdf CDSO Checklist

1 Remarks *

NA

2. Justification of Quantity

2. Justification of Quantity *

Select Document Type

Supported files are PDF

Form 2
CT12-ND-FFBD-Test & Analysis-Checklist

Checklist

1. Covering Letter of the firm *

Select Document Type

Supported files are PDF

1. Covering Letter of the firm - Remarks *

2. Self attested by Head of the institution proprietor or director of the company or firm (with authority letter)Copy of manufacturing licenses in form -25/28/28D or loan license issued by SLA or DSIR approval in case of R6D.

Select Document Type

Supported files are PDF

2. Self attested by Head of the institution proprietor or director of the company or firm (with authority letter)Copy of manufacturing licenses in form -25/28/28D or loan license issued by SLA or DSIR approval in case of R6D - Remarks *



सत्यमेव जयते

What are the technical Requirements for NSWS

System Requirements for National Single Window Portal

- Windows OS (XP or higher)
- MAC OS (X 10.9 or higher with latest updates)
- **View/ Download Pdf:** Download the pdf reader to view and download the pdf files from the link: <https://get.adobe.com/reader/>)
- Platform requires a minimum screen size of 976px wide , but using 1024px or higher is recommended
- **Digital Signature Certificate (DSC):** Latest version of emBridge software need to be installed in the system which acts a connecting link/driver between the NSWS and DSC

Web browsers best suited for National Single Window System

- Google Chrome
- Mozilla Firefox
- Apple Safari

Have any further questions?

Please submit your queries and feedback on:

<https://www.nsws.gov.in/contact-us>

Email: contactus-nsws@investindia.org.in

Ph: 1800 102 5841

(Monday - Saturday, 9am - 6pm)

Last Updated on 14 March 2023