



STANDARD OPERATING PROCEDURE

**Subcommittee under Empowered Committee for Animal Health (ECAH)
for Examination of Proposals Referred by CDSCO for Veterinary Drugs,
Vaccines/Biologicals including IVD kits and Medical Devices**

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

ABSTRACT

This document lays down the Standard Operating Procedures (SOP) for examination of proposals related to the import and approval of veterinary drugs, vaccines/biologicals, in vitro diagnostic (IVD) kits, and medical devices for animal health, as referred to the Department of Animal Husbandry and Dairying (DAHD). It describes the procedures for submission, receipt, and forwarding of applications, as well as the process of technical examination and deliberation undertaken by the Empowered Committee for Animal Health (ECAH) Subcommittee.

The SOP provides clear guidance on submission of applications through the Central Drugs Standard Control Organization (CDSCO), including routing through the designated online platforms, and outlines the mechanism for dossier scrutiny, expert consultation, and documentation of recommendations. These procedures are intended to ensure clarity, consistency, transparency, and accountability in the technical examination process.

The purpose of this document is to establish a structured and systematic approach for handling proposals and facilitating timely and fair technical evaluation of animal health-related products. The SOP defines roles and responsibilities, specifies steps for dossier handling and expert review, and sets out the process for recording decisions and follow-up actions with firms or research institutions, as required.

Overall, this SOP outlines the procedures to be followed for processing and technical examination.

1. Objective

To lay down a uniform, transparent, time-bound and well-documented procedure for examination of proposals referred by the Central Drugs Standard Control Organization (CDSCO) to the Department of Animal Husbandry and Dairying (DAHD) through the ECAH Subcommittee, and for issuance of technical advice /recommendation/ No Objection Certificate (NOC) wherever required.

2. Legal Framework and Mandate

2.1 CDSCO, under the Drugs and Cosmetics Act, 1940 and Rules, 1945, is the statutory authority for licensing of drugs, vaccines/biologicals, and medical devices, including veterinary products.

2.2 DAHD's role is purely advisory, limited to providing technical inputs on essentiality, desirability and examining safety and potency data of veterinary products in the Indian animal health context.

2.3 The ECAH Subcommittee examines only those proposals formally referred by CDSCO and furnishes DAHD's technical recommendations to CDSCO.

3. Empowered Committee for Animal Health (ECAH) Subcommittee

3.1 Background

Established in 2021, the Empowered Committee for Animal Health (ECAH) functions as the apex technical advisory body of DAHD, providing guidance on animal Health related issues, and matters related to veterinary pharmaceuticals and biologicals.

3.2 Mandate of the Subcommittee

A Subcommittee under ECAH is constituted to examine proposals received from the Central Drugs Standard Control Organization (CDSCO) related to veterinary drugs, veterinary vaccines/biologicals including IVD kits and medical devices, etc. to furnish technical comments/advice from the Department of Animal Husbandry and Dairying.

3.2. Composition of the ECAH Subcommittee

- a. Animal Husbandry Commissioner, DAHD – Chairman
- b. Member from ICAR
- c. Member from CDSCO
- d. Member from Indian Pharmacopoeia Commission
- e. Member from Livestock Health Division
- f. Expert in Poultry medicine/Medicine /pharmacology/microbiology (4-5)

3.3 Terms of Reference (ToR) of the ECAH Subcommittee

- To examine proposals referred by CDSCO relating to veterinary drugs, vaccines/biologicals, IVD kits, and medical devices.
- To provide technical comments/advice from DAHD to CDSCO.
- To allow participation of applicant only for their specific agenda item
- Meetings to be held twice every month.
- Minimum quorum: Five (5) members.

4. Scope of SOP

This SOP applies to proposals related to:

- Veterinary drugs
- Veterinary vaccines / biologicals including Veterinary diagnostic kits
- Medical devices /

5. Requirement of DAHD NOC

5.1 NOC from DAHD is MANDATORY for:

A. Veterinary Vaccines / Biologicals

- New strain or new source
- New manufacturing technology (live, inactivated, recombinant, vectored, r-DNA, sub-unit)
- Genetically modified or recombinant products
- New combination/ New formulation (even if individual strains are approved earlier)

B. Veterinary Drugs

- New chemical entities
- New formulations with safety/efficacy implications
- New route of administration
- First-time use in food-producing animals

C. Veterinary Medical Devices

- Not previously examined for veterinary use in India
- Involving new or modified technology affecting safety or usability
- Having potential implications for biosafety or animal welfare

5.2 NOC from DAHD is NOT REQUIRED for:

- Same strain from the same approved source
- Generics of approved veterinary drugs
- Devices with approved predicates
- Existing indications (unless new species or major change)

6. Application Flow

6.1 Submission by Firm

- Application submitted only to CDSCO through SUGAM portal

6.2 Forwarding by CDSCO

- CDSCO forwards proposal to DAHD:
 - Online (SUGAM / NANDI) – preferred
 - Offline (official email with checklist) – exceptional
- CDSCO shall clearly specify whether an NOC from DAHD is required and, if so, clearly indicate the specific purpose for which the NOC or technical comments are sought, including the exact issues or aspects on which DAHD's inputs are required.

7. Dossier Receipt and Completeness Check

7.1 Applicant uploads full dossier through SUGAM credentials.

7.2 DAHD reviews dossier completeness within 5 working days.

If complete:

→ Agenda of next subcommittee meeting

If incomplete:

→ Deficiency communicated; 10 working days given for compliance.

→ Processing timelines start only after complete dossier is received.

→ Re-examination of compliance-with 3 working days

8. Registration and Agenda Finalisation

8.1 Each complete proposal allotted unique registration number.

8.2 **Agenda inclusion timelines:**

- New cases: ≥ **10 days** before meeting
- Deferred cases: ≥ **5 days** before meeting

9. Pre-Meeting Expert Review

9.1 Dossiers circulated electronically/NANDI to members 10 days before meeting.

9.2 The firm shall submit a presentation to DAHD, in advance, after submission of the complete dossier, if required.

9.3 External experts provide written comments within **7 days, if any observation information is required.**

10. Conduct of Subcommittee Meeting

10.1 Preferably on the 1st and 3rd Tuesday of every month. In case of a holiday, the meeting will be held on the next working day.

10.2 Meeting Sequence

1. Quorum confirmation
2. Conflict of interest confidentially declaration
3. Agenda wise presentation
4. Firm presentation (if invited)
5. Closed expert deliberation
6. Decision recording

10.3 Possible Decisions

- Recommended (NOC)
- Recommended with conditions
- Deferred – for comments firm
- Deferred – for experts opinion of research institute
- Rejected
- Additional expert opinion required

11. Minutes of Meeting (MoM)

- 11.1 Draft MoM prepared within 5 working days.
- 11.2 Circulated to members for comments (2 working days for comments).
- 11.3 Reminder to experts for comments
- 11.3 No response in 3 days = deemed approval.
- 11.4 Final MoM approved by Chairperson

12. Communication of Decisions

12.1 Based on approved MoM, DAHD issues:

- NOC / Conditional NOC to CDSCO
- Non-recommendation to CDSCO
- Deferral queries to firm/Experts

12.2 **Timelines:**

- NOC / rejection/observations: **within 30 days**

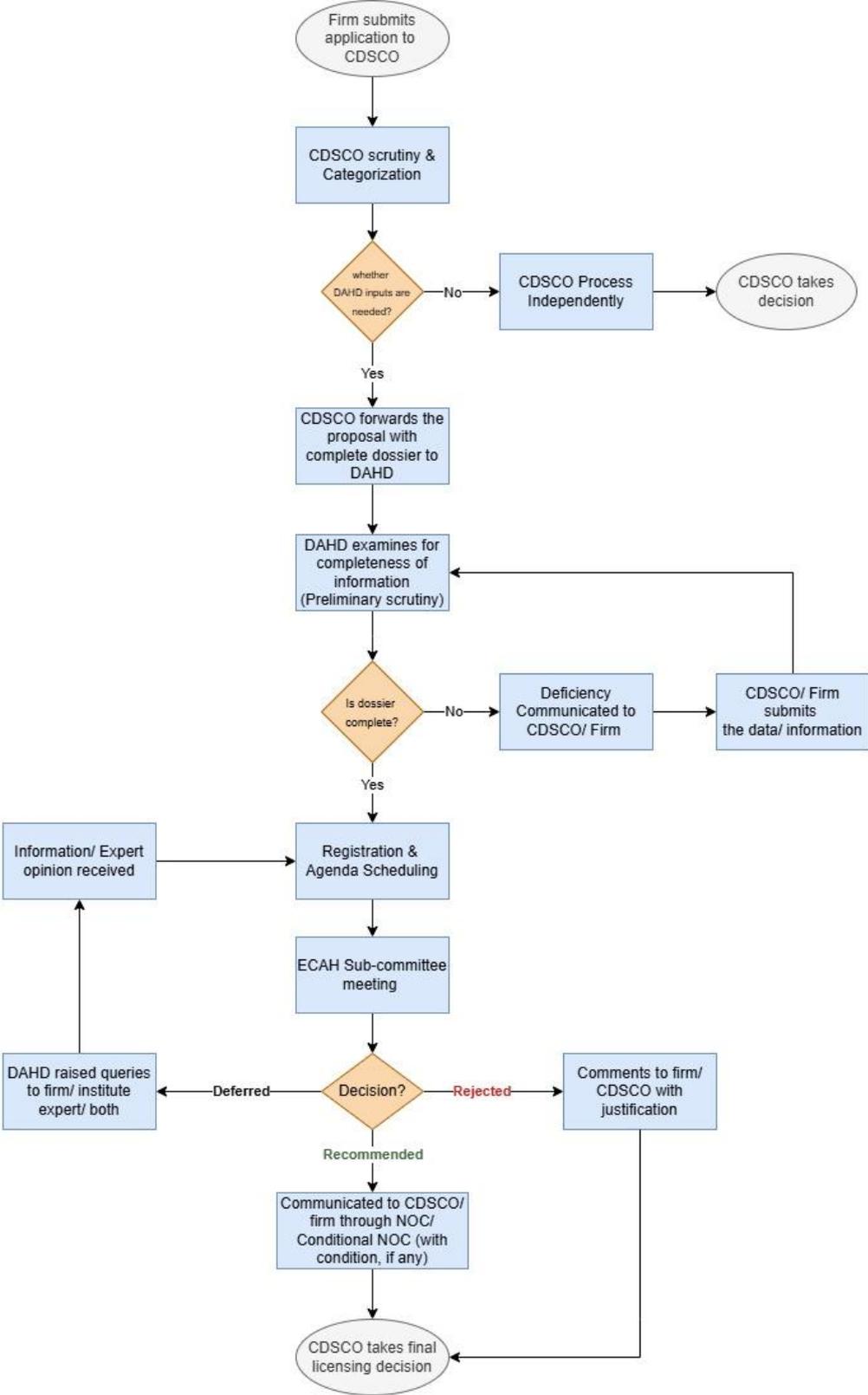
12.3 All communications routed online with CDSCO in copy

13. Confidentiality and Conflict of Interest

- Members with a conflict of interest shall not participate in the deliberations or decision-making on the concerned agenda.
- Proprietary and confidential data shall be protected.
- No public disclosure; decisions communicated only through CDSCO.

14. Clarification: DAHD NOC is **not a statutory licence** and **does not substitute CDSCO approval**

Steps in approval process in DAHD



Annexures

Annexure – I

Time Charter for Processing of Proposals Referred by CDSCO to DAHD through the ECAH Subcommittee

This Time Charter is to provide indicative, facilitative timelines for processing of proposals referred by the Central Drugs Standard Control Organization (CDSCO) to the Department of Animal Husbandry and Dairying (DAHD) through the ECAH Subcommittee, with the objective of promoting administrative efficiency, transparency, and predictability, without compromising technical scrutiny, biosafety, or public and animal health safeguards.

a. Processing of proposals shall at all times remain subject to:

- Submission of complete data of acceptable quality, in accordance with the prescribed checklist
- Availability of relevant expert inputs for technical evaluation
- Compliance by the applicant with applicable regulatory and procedural requirements
- Administrative and technical exigencies, as may arise during examination of the proposal

b. Stage-wise Indicative Timelines

3	Receipt of proposal in DAHD from CDSCO, clearly indicating whether DAHD NOC and/or technical advice is required, accompanied by a duly filled checklist as prescribed by DAHD	CDSCO	
4	Completeness and checklist scrutiny of dossier	DAHD	Within 5 working days
5	Communication of deficiencies (if any)	DAHD	Within 5 working days
6	Submission of deficiency compliance	CDSCO/Applicant	Within 10 working days
7	Re-examination of compliance	DAHD	Within 3 working days
9	Circulation of dossier to Subcommittee members and experts	DAHD	At least 10 days prior to meeting
10	Receipt of written comments from external experts (in case of nonreceipt of comments from external	Experts	Within 7 days

	experts they will be invited for comments in ECAH subcommittee meeting)		
11	Convening of ECAH Subcommittee meeting	DAHD	1st and 3rd Tuesday
13	Preparation of draft Minutes of Meeting	DAHD	Within 5 working days
	Comments of experts on draft MoM	DAHD/Experts	Within 2 working days
	Reminders	DAHD	1 working day
	Finalisation and approval of MoM	DAHD	Within 3 working days
	Issuance of DAHD communication (NOC / conditional NOC / observations / rejection) to CDSCO	DAHD	Within 30 days from receipt of complete dossier

Any request for clarification, additional data, re-analysis, or expert opinion shall **pause the processing clock**, which shall recommence only upon receipt of satisfactory inputs.

c. Exclusions from Timelines

The following periods shall be **explicitly excluded** from computation of processing time:

- Time taken by the applicant to submit deficiency compliance
- Time taken for receipt of additional data, revised dossiers, or explanations
- Holidays, force majeure events, or circumstances beyond the control of DAHD

d. Comments of external experts

In the event of non-receipt of expert comments within the indicative timeline, the Subcommittee may proceed on the basis of available inputs or, as considered appropriate, recommend one or more of the following actions, with reasons duly recorded:

- Invite the concerned expert(s) for on-record deliberation
- Seek inputs from alternate experts or recognised institutions
- Defer the proposal with reasons duly recorded.

All recommendations of DAHD shall be communicated in writing only after approval of the competent authority.

The timelines and processes outlined in this Time Charter are intended for internal administrative guidance only and shall not be enforceable as a matter of legal right by any applicant or stakeholder.

Checklist for Drugs/vaccine

Checklist for submission of dossier in uniform and Concise format by the firms for import/manufacture of drugs/vaccines/biologicals

The checklist for submission of dossier in Summary/Concise format by the firm for import/manufacture of drugs/vaccine/biological is as follows (Data/proof for all claims to be included)

1. Name of the product (details in case of microbes like serovars, strains, variants)
2. Manufacture/Import from Country (In case of import – Place of manufacture & name of the country/source)
3. Justification/reasons for import
- 4. General Requirement**
 - i. Target species
 - ii. Composition
 - iii. Active ingredient(s)
 - iv. Indications for use**
 - v. Dose**
 - vi. Potency/Titer
 - vii. Route of administration**
 - viii. Onset and duration of immunity
 - ix. In case of combo vaccines/drugs advantages over single product
 - x. In case of change in drug composition or vaccine Strain-reasons to be given (with proof for justification)
 - xi. Contradictions/precautions if any (Special warning/precaution for each target species)
 - xii. Adverse reaction (frequency and seriousness)
 - xiii. Use during lactation/pregnancy/layers/Broiler Breeder
 - xiv. Overdose reactions/ margin of safety
 - xv. Shelf life (Specify Temperature)

- i. Summary on Efficacy claims and study data
 - ii. Laboratory efficacy claims
 - iii. Summary on studies of safety
 - iv. Pharmacological properties
 - v. Studies/publications/ homology related to prevalence of strain(s) in the country against which intended to be used
 - vi. Clinical trial data
 - vii. In case of change in drug composition or vaccine Strain-safety/efficacy studies related to the proposal
6. Use in other Countries, if used/registered/patented (Patent details) along with names of countries
 7. Rejected/ banned by any country
 8. Narcotics /any banned substance.
 9. Whether it is GM product, give details.
 10. Environmental impact/shedding period and mode
 11. Novel strain, first time Import-Advantage over present vaccine strains available in India.
 12. Labelling –withdrawal period in case of drugs/any other safety requirement /precaution, indication, contraindication.
 - 13. Excretion in milk in livestock/ eggs in poultry**
 14. Maximum residual effects in case of animal drug; time withdrawal recommended if any (with details)
 15. Is the firm /trader able to monitor the usage through retailers or is it possible for them to trace back or recall in case of any problem
 16. Whether the product is as per standards given in Indian Pharmacopeia-2018 (**Latest edition**) or any other standard(**specify**)
 17. What is the utility of the product is for the Indian animal health sector and how this product is novel.
 18. Any publications to support the claims on the product (If yes, please provide the reference)
 19. Impact of drugs/vaccine on environment / human/animal

Checklist for CDSCO”

CDSCO to submit following information before submitting proposals to DAHD for thorough and smooth facilitation in examining the proposals effectively:

Name of the Product	Comments of CDSCO
Whether similar product is already approved in the country	
Whether same strain/serotype is already approved by CDSCO	
Whether the source is same or different	
If yes, the reason for referring the case to DAHD	
The specific points on which the comments have been sought from DAHD for already approved products	

The Department will accept the invitation upon receipt of the above information along with the application. This would greatly facilitate the Department in providing recommendations promptly.

Checklist for Import of In Vitro Diagnostic (IVD) Kits for Veterinary Use in India

Category	Checklist Items	Remarks
1. General Information		
Product Name with description and Intended Use	State the name and intended use of the IVD kit.	Clearly specify the diagnostic purpose.
2. Product Description		
Kit Type	Type of diagnostic kit (e.g., Serology and Immunology Diagnostic Kits, ELISA, RT-PCR, Lateral Flow etc) or for in vivo use.	
Target Species	Specify the animal species intended for use	
Intended Application	Screening, confirmatory, or quantitative/qualitative test etc	
Kit Components	Provide a list of kit components (e.g., reagents, control samples etc). including type of antigen live pathogen /inactivated /recombinant antigen or serum or monoclonals	
Is the product marketed elsewhere? If so, provide a list of countries where the product is marketed		
3. Technical and Scientific Data		
Sensitivity and Specificity	Provide sensitivity, specificity, and validation reports.	
4. Compliance with Regulatory Standards		
International Certification	Compliance aligns with international standards such as	

	those outlined by WOA (World Organisation for Animal Health)	
Infectious Agent Certification	Certification confirming that the product and its components are free from infectious agents (e.g., bacteria, viruses, fungi) and comply with BSE/TSE-free requirements.	Supplier must provide certification if uses any animal origin product during manufacturing of the device.
Animal-Origin Compliance		
Risk Assessment	Submit documentation on biohazards and environmental risks.	
5. Validation and Field Trials		
Validation Data	Evidence of validation in India or internationally.	
<p>Executive Summary: A summary of key supporting documentation. Every Please provide an introductory text or narratives to help connect the submitted documents. Any exceptions or unusual circumstance which the firm wishes to highlight, specific to the product or application, should be mentioned in the Executive Summary.</p>		

Checklist for Import of Medical Device for Veterinary Use in India

Category	Checklist Items	Remarks
Product Name with description		
1. Essentiality and Desirability		
Intended Use	Specific purpose of the device (e.g., diagnosis, treatment, monitoring, surgery etc.).	
Target Species	Animal species intended for the device.	
Market Availability	<ul style="list-style-type: none"> • Availability of similar devices in the domestic market/Upgraded Model/ apart from existing products. • Highlight any upgraded features or novel aspects/ advantage compared to existing products. 	
Is the product marketed elsewhere? If so, provide a list of countries where the product is marketed		
2. Disease Risk Prevention		
Safety Measures	Compliance with international safety standards (e.g., ISO, WOH, CE, FDA).	BIS mandatory for Make in India products.
Infection-Free Certification	Certification confirming that the product and its components are free from infectious agents (e.g., bacteria, viruses, fungi) and comply with BSE/TSE-free requirements.	Supplier must provide certification if uses any animal origin product during manufacturing of the device.

Category	Checklist Items	Remarks
Associated risk of contamination/spread of infection during use		
3. Regulatory Compliance		
International Certification	Compliance with international safety standards (e.g., ISO, WOH, CE, FDA or any other reputed international organization).	BIS mandatory for Make in India products.
Adherence to Standards	Compliance with international safety standards (e.g., ISO, WOH, CE, FDA Electro Technical Commission (IEC), or other pharmacopeia standards.	
4. Technical Specifications		
Documentation	<ul style="list-style-type: none"> i. Complete technical dossier (design, composition, operational guidelines) ii. Safety and Effectiveness Studies iii. Ensure the device performs as intended, with data on accuracy, precision, and sensitivity iv. Guidelines for disposal after use 	
5. Environmental and Ethical Considerations		
Environmental Impact	Guidelines for disposal of hazardous waste (if any)	
<p>Executive Summary: A summary of key supporting documentation. Every Please provide an introductory text or narratives to help connect the submitted documents. Any exceptions or unusual circumstance which the firm wishes to highlight, specific to the device or application, should be mentioned in the Executive Summary</p>		

Annexure VI:

Template for Minutes of Meetings shared with experts of ECAH Subcommittee

Minutes of the Meeting of Empowered Committee for Animal Health (ECAH) Regulatory Subcommittee

The meeting of the Empowered Committee for Animal Health (ECAH) Regulatory Subcommittee to assess and provide recommendations and policy inputs on the proposals received in the department for the import and manufacturing of veterinary vaccines/biologicals/drugs was held on xxxxxx at xxxx under the chairmanship of Animal Husbandry Commissioner (AHC), DAHD. The list of participants is enclosed in **Annexure-A**.

Firm Name	Agenda	Strain/ Vaccine/ Active Ingredient	Target Species	Discussion	Decision



