BULK DRUG MANUFACTURES ASSOCIATION (INDIA)

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Circular No. BDMA/093/2026 **Date: 18th Nov 2026**

Dear Sir

Sub: Minutes of the Meeting of Quarterly Review Meeting of CDSCO held on 24.8.2026

As members are aware, CDSCO conducted a Quarter Review Meeting on 24th August 2026. Based on the inputs received from members, BDMAI submitted a consolidated issues of the industry to CDSCO for discussion in the meeting. The issues raised were duly discussed in the meeting.

We enclose herewith the minutes of the above meeting for information of members. In case of some of the issues, CDSCO advised to bring specific issues to the notice of IND Division. Members may please take note of the same.

With regards

M Roja Rani
Executive Director

Be a Part of BDMAI
e-Marketing Portal of Indian Bulk Drugs

F. No. RTI-11013(12)/32/2026-eoffice
Government of India
Ministry of Health & Family Welfare
Central Drugs Standard Control Organisation (CDSCO)
FDA Bhawan, Kotla Road, New Delhi – 110002

Date:
10 NOV 2026

To,
All Concerned Stakeholder Associations

Subject: Minutes of meeting (MoM) of the first quarterly stakeholder meeting held on 24.08.2026 – reg.

Sir/Madam,

With reference to the first quarterly stakeholder meeting held on 24.08.2026 at CDSCO (HQ), FDA Bhawan, New Delhi, please find enclosed herewith the Minutes of the Meeting for your kind information and reference.

All concerned stakeholders are requested to take note of the deliberations and recommendations recorded in the Minutes.

Yours faithfully,

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

Copy to:

1. Under Secretary, Drugs Regulation Section, Ministry of Health
2. CDSCO website

Minutes of Meeting

of

Quarterly Stakeholder Meeting with CDSCO (Chaired by DCGI)

Held at CDSCO(HQ), FDA Bhawan

Date: 24.08.2026

With a view to strengthening stakeholder engagement, enhancing transparency, improving regulatory compliance, and facilitating effective dissemination of recent regulatory developments, the Central Drugs Standard Control Organisation (CDSCO) had proposed to organize Quarterly Meetings with Stakeholders under the Chairmanship of the Drugs Controller General (India) (DCGI).

Accordingly, vide letter No. RTI-11013(12)/32/2026-eoffice (39116) dated 06.08.2026, CDSCO requested the following associations to nominate not more than two representatives each to participate in the meeting with the Drugs Controller General (India), scheduled on 24.08.2026:

S. No.	Association	Full Name
1	IDMA	Indian Drug Manufacturers' Association
2	OPPI	Organisation of Pharmaceutical Producers of India
3	BDMA(I)	Bulk Drug Manufacturers Association (India)
4	FOPE	Federation of Pharma Entrepreneurs
5	IPA	Indian Pharmaceutical Alliance
6	FICCI	Federation of Indian Chambers of Commerce and Industry
7	CII	Confederation of Indian Industry
8	IVMA	Indian Vaccine Manufacturers Association
9	HDMA	Himachal Drug Manufacturers Association
10	LUB	Laghu Udyog Bharati
11	INFAH	Indian Federation of Animal Health Companies
12	VVIMA	Veterinary Vaccine India Manufacturers Association.
13	KDPMA	Karnataka Drugs & Pharmaceutical Manufacturers
14	Pharmexcil	Pharmaceuticals Export Promotion Council of India

Further, the said associations were also requested to forward brief discussion points in advance, in order to facilitate the meeting and enable it to be organized in a systematic manner. Accordingly, the industry associations submitted their respective discussion points, along with the issues identified and the way forward suggested by them.

The issues so submitted by the associations were subsequently placed before the meeting for discussion with the nominated representatives of the associations, under the Chairmanship of the Drugs Controller General (India).

Participants:

Associations	**CDSCO**
1) Mr. Namit Joshi, PHARMEXCIL 2) Mr. Ashok Madan, IDMA 3) Mr. Harish K. Jain, FOPE 4) Mr. Rajesh Madan, FOPE 5) Dr. Azdar Khan, IPA 6) Dr. Amit Talwar, IPA 7) Mr. Surinder Kher, FICCI 8) Dr. Ajay Sharma, CII 9) Ms. Yasmin Shenoy, CII 10) Mr. Rakesh Arora, HDMA 11) Mr. S. Singhal, HDMA 12) Mr. Ashok Kumar Sharma, IVMA 13) Mr. S. Sravan Gundabathula, IVMA 14) Mr. Rajiv Gandhi, VVIMA 15) Mr. Vijay Teng, INFAH 16) Dr. Manoj Sood, INFAH 17) Dr. Rajesh Gupta, LUB 18) Mr. Rohit Bhatia, LUB 19) Ms. Sukanya Chodhry, OPPI	1) Dr. Rajeev Singh Raghuvanshi, DCG(I) (Chairperson) 2) Dr. A Visala, JDC(I) 3) Mr. Ranga Chandarshekar, JDC(I) 4) Mr. Sunil Kulshrestha, DDC(I) 5) Dr. Rubina Bose, DDC(I) 6) Dr. Jayant kumar, DDC(I) 7) Ms. Swati Srivastava, DDC(I) 8) Mr. Sanjeev Kumar, DDC(I) 9) Mr. Ankit Sharma, DDC(I) 10) Mr. Gaurav Kumar, DDC(I) 11) Mr. Mukesh Kumar, ADC(I) 12) Mr. D. V. Singh, ADC(I) 13) Ms. Nisha Sankhwar, ADC(I) 14) Dr. Jay Jyoti Roy, ADC(I) 15) Mr. Saurabh Garg, ADC (I) 16) Ms. Suniti Choudhary, DI 17) Mr. Chandrashekar, DI 18) Mr. Shivraj Subhash Sulgudle, DI

The Drugs Controller General of India (DCGI) welcomed the nominated representatives of the participating industry associations and outlined the purpose and objectives of the meeting**.**

The DCGI emphasized the importance of continued and structured engagement between the regulatory authority and industry stakeholders to promote transparency, strengthen regulatory compliance, facilitate effective communication and dissemination of recent regulatory developments, and provide an appropriate platform to understand and address stakeholder expectations and concerns. This was followed by a formal introduction of all participants**.**

CDSCO presented the recent regulatory initiatives, reforms and developments undertaken by the organization, with the objective of apprising stakeholders of key changes and facilitating their effective implementation.

Subsequently, the issues and proposals submitted by the participating industry associations were taken up for item-wise discussion and deliberation**.** The points raised by the associations, the discussions held, and the observations/decisions of CDSCO are detailed below.

S. No	Issue Title	Assoc.	Issue Identified	Suggested Way Forward	Recommendation made during the meeting
1	**Stability Data for Export BE NOC**	BDMAI	Requiring three months of GMP-batch stability data before notification for an export BE NOC can delay project execution.	Allow stability data to be submitted after notification but prior to initiation of the BE study.	CDSCO apprised the stakeholders related to recent reform introducing a notification-based process for BA/BE studies conducted for export purposes, in place of prior approval, with the objective of reducing timelines and promoting ease of doing business. However, CDSCO did not agree with the proposal to

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					permit submission of stability data after notification but prior to initiation of the BE study for export purposes.
2	**Form 28D/ 28DA Licence Delays**	BDMAI / IVMA	Delay by SLA to issue Form 28D/28DA licenses & 2–3 extra months for CLA countersignature, consuming much of the export NOC's one-year validity.	State and Central recommendations are issued jointly after inspection, delegate final license issuance authority to the SLA.	Apprised the stakeholders that the implementation of the ONDLS portal has reduced timelines for the issuance of Form 28D/28DA as compared to the previous paper-based system. CDSCO further agreed to address any specific issues pertaining to the ONDLS portal in order to further streamline the timelines for issuance of Form 28D/28DA. However, the proposed procedural modification has not been accepted by CDSCO.
3	**Risk-Based Export NOC Categories**	FOPE	Restriction of Export NOC requirements to high-risk categories, such as NDPS and other specifically identified high-risk drugs.	—	Stakeholders were apprised about the recently implemented digital Export NOC system, under which the process has transitioned from consignment-based

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					approvals to product-level NOCs valid for a period of one year. This system has enabled greater transparency, quota tracking, and prevention of illegal exports. However, CDSCO did not agree with the proposal to restrict Export NOC requirements to high-risk category drugs only.
4	**Delegation of EU Written Confirmation Authority**	BDMAI	CDSCO HQ may take 2–3 further months to grant EU Written Confirmations after Zonal Office recommendation, with repeat queries adding more delay.	Delegate authority to issue Written Confirmations to Deputy Drugs Controllers, where appropriate, to cut processing time.	CDSCO informed the stakeholders that the recently published SOP for review of Written Confirmation (WC) applications has removed the earlier dual-review system (at both the Zonal and Headquarters levels). Under the revised SOP, Zonal Offices are required to verify that the documents against each checklist point have been correctly and legibly uploaded by the applicant and to conduct an onsite

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					inspection to verify compliance with Good Manufacturing Practices as applicable; verification of the adequacy of documents is not required at the Zonal/Sub-Zonal level. The adequacy of the documents submitted is only reviewed at the Headquarters level to streamline the processing timelines. However, the proposed procedural modification has not been accepted by CDSCO.
5	**Defined Export Pathway for Vaccines**	IVMA	There is no clearly defined process or timeline for reviewing and issuing vaccine Export NOCs.	Establish a defined process and indicative timeline; consider one-time NOCs not tied to specific quantity/destination, where appropriate.	CDSCO apprised the stakeholders that a clearly defined process and timeline for the review and issuance of vaccine Export NOCs is already available. Stakeholders were requested to bring forward any specific cases, and the Vaccine Division was directed to resolve any

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					specific issues raised by the stakeholders.
6	**Multi-Agency Field-Trial Approvals**	VVIMA	Field-trial approvals need sequential review by CDSCO, DAHD, ECAH and IVRI, causing duplication, unclear accountability and delays.	Adopt a single Subject Expert Committee (SEC) mechanism, with CDSCO/DAHD as the accountable decision-making authority.	Stakeholders informed that DAHD was raising repeated queries to the applicant and requested that a single Subject Expert Committee (SEC) mechanism be adopted, with CDSCO/DAHD as the accountable decision-making authority. Stakeholders were informed that the veterinary division had started sharing the complete tech pack with DAHD to avoid repeated queries by DAHD. Stakeholders also raised concerns about a potential conflict of interest on the part of DAHD, as it is involved in developing and commercializing the technologies. CDSCO informed stakeholders that adoption of

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					a single SEC under CDSCO for deliberation of veterinary applications requires inter-ministerial consultation.
7	**Vaccine Efficacy & Challenge-Study Duplication**	VVIMA	Efficacy/challenge studies are treated as manufacturer-specific even when the strain is already validated by IVRI or GoI institute.	Recognise validated GoI-institute strain data; waive repeat challenge studies where comparability is shown via serology and other data.	It was recommended to consider the Efficacy/challenge studies data only after the regulatory intervention, on a case-by-case basis. The data generated before the regulatory intervention may not be considered for filing purposes.
8	**Phase I Batch Requirements for NCEs**	BDMAI / CII	Three batches (incl. two pilot-scale) are required for Phase I trials, though the goal at this stage is safety/tolerability, not commercial consistency.	Accept one representative cGMP batch (lab/small-scale where justified) for Phase I, focused on clinical batch quality, not commercial-scale consistency.	It was informed that, in practice, CDSCO does not insist on three batches (including two pilot-scale batches), full process validation, method validation, or comprehensive impurity specifications for Phase I/II trials. However, stakeholders were requested to bring any specific concerns to the

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					IND Division for further resolution.
9	**Validation at Phase I/II Stage**	BDMAI / CII	Full process validation and method validation may be required while the manufacturing process is still evolving, adding cost and delay.	Allow a phase-appropriate approach without full formal process validation at Phase I/II; verify parameters such as specificity and accuracy and defer full validation until appropriate later development stages.	It was informed that, in practice, CDSCO does not insist on three batches (including two pilot-scale batches), full process validation, method validation, or comprehensive impurity specifications for Phase I/II trials. However, stakeholders were requested to bring any specific concerns to the IND Division for further resolution.
10	**Early-Phase Impurity Specifications**	BDMAI	Comprehensive impurity specs are required early in clinical development, without flexibility for establishing appropriate impurity limits at the early clinical development stage.	Set initial impurity limits from toxicological-batch data, refined progressively using clinical-batch and process-development data.	It was informed that, in practice, CDSCO does not insist on three batches (including two pilot-scale batches), full process validation, method validation, or comprehensive impurity specifications for Phase I/II trials. However, stakeholders were requested to bring any specific concerns to the IND Division for further resolution.
11	**Local Agent Change — Import**	OPPI	For a change of local agent's name/address on the IL & RC, the existing	Extend the submission window to 180 days from 90 days; keep the	CDSCO decided to take up the matter for further

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	license (IL) & Registration Certificate (RC)		permission stays valid for only three months during processing.	existing IL/RC valid until CDSCO decides on application; treat these changes as amendments; retain existing RC/IL numbers.	discussion in the Internal Technical Committee.
12	**Regulatory Pathway for Recombinant Vaccines**	CII / INFAH	Veterinary recombinant vaccines may involve CDSCO/DCGI, State Controllers, DAHD, DBT and MoEFCC, causing overlapping requirements and an unclear pathway.	Establish a coordinated mechanism or dedicated committee, with a clear pathway for development, registration and approval.	It was informed that the process for creating the Digital Drug Regulatory System (DDRS), a unified single-window platform, has already been initiated. CDSCO informed that, as the concern raised involves multiple agencies under different ministries, inter-ministerial consultation is required to devise a suitable mechanism.
13	**IP Compliance for Combination Vaccines**	CII / INFAH	Each component of a new combination vaccine must meet the IP monograph, difficult where it was validated to a different standard abroad (IH/ other Pharmacopeia).	Allow regulatory flexibility or exception when developed and validated as per a recognized pharmacopoeia standard or an accepted method in the country of origin.	Stakeholders were requested to bring any specific concerns to the Veterinary Division for further resolution.

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14	**Veterinary Use of Registered Bulk Drugs Substance (DS)**	CII / INFAH	DS already registered by Import Division and used in both human and veterinary formulations and meeting applicable specifications may still need a separate registration for veterinary import.	Permit import for veterinary use without separate registration where the bulk drug is already registered and compliant.	CDSCO decided to take up the matter for further discussion in the Internal Technical Committee.
15	**Consolidated List of Approved Drugs & FDCs**	FOPE	There is no single consolidated list of approved single drugs and FDCs covering approved drugs by DCGI, Kokate Committee, pre-1988, IP/NFI and vitamin-combination.	—	Stakeholders were informed that the process for preparation of a consolidated list of approved drugs, including FDCs, has been initiated. Stakeholders were urged to submit pre-1988 approval data, along with supporting evidence, for further necessary action.
16	**Status Clarification for IP-Listed Formulations**	FOPE	Prior to 2013-word IP existed in New Drug definition & It is unclear whether formulations listed in the IP should be treated as approved or unapproved.	Deemed approvals following inclusion in the Indian Pharmacopoeia (IP), National Formulary of India (NFI).	It was recommended that drugs listed in the I.P. 2010 may be deemed to be approved drugs.
17	**BA/BE Notification —**	FOPE / LUB	BA/BE notification G.S.R. 327(E) Published in 2017 (RLD list published in Jan	Clarify that the requirement applies prospectively only after	CDSCO did not agree with the proposal.

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	Prospective Applicability		2020) is being applied retrospectively in practice, as firms are receiving notices for past products.	January 2020, only to products with an officially notified reference product.	
18	**Legacy Facilities Under Revised Schedule M**	FOPE	Existing legacy manufacturing facilities face practical challenges implementing certain Revised Schedule M provisions.	Consider suitable alternative compliance mechanisms where justified; a subcommittee could examine practical implementation challenges, run regular QA/QC/Production certificate courses.	It was informed that consideration may be given on a case-by-case basis, by assessing the risk to the quality of the drug. Stakeholders were further informed that such matters are being taken up before the Internal Technical Committee for deliberation with senior officials of CDSCO.
19	**Publishing FAQs on Recurring Issues**	FOPE	Recurring regulatory and procedural issues create uncertainty among stakeholders about applicable requirements.	Publish comprehensive FAQs on the CDSCO website addressing recurring regulatory and procedural issues.	FAQs on various matters are being published on the website from time to time. No further action is recommended in the matter.
20	**License Cancellation Decisions**	FOPE	SLAs cancel product permissions based on joint-inspection recommendations that may rest on incomplete data or do not adequately consider the regulatory status of pre-1988 drugs.	Opportunity by SCN as per Rule 85 before regulatory action.	It is informed that SLAs are following the procedure laid down under Rule 85 of the Drugs Rules before cancellation and suspension action.

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21	**Classification Under NDCT Rules, 2019**	LUB	Gastro-resistant/delayed-release tablets/capsules are treated as "new drugs" under the NDCT Rules 2019, raising concerns about retrospective withdrawal of earlier approvals.	Requested for instructions and guidance on this issue.	CDSCO did not agree with the proposal.
22	**Monthly Publication of SQ & NSQ Data**	LUB	Monthly publication of NSQ data may create undue concern for MSMEs and be misread by the public and international regulators.	Give the concerned company an opportunity to respond before publication, and publish a monthly Standard Quality (SQ) drug list alongside NSQ data.	CDSCO did not agree with the proposal.
23	**Resolving ONDLS Platform Issues**	BDMA I / LUB	Companies have raised issues with the ONDLS system, including matters relating to WHO GMP/CoPP and Form 28D licences.	Examine the specific issues raised by companies and take appropriate action, as applicable.	Stakeholders were requested to bring any specific concerns to the IT Division for further resolution.