S.No	Points	Existing provision under Drugs & Cosmetics Act and Rules thereunder (if any)	Issues Identified	Way Forward
1	EU Written Confirmations	As per the guidelines, EUWCs are to be issued by CDSCO, New Delhi after recommendation from CDSCO, Zonal office as per prescribed times lines.	Post recommendation from CDSCO, Zonal offices, CDSCO, New Delhi is taking another 2 to 3 months for granting permissions. Sometimes, CLA is raising queries to the companies and most of the times information to such queries is already available in the file and this causing further delays in getting the EUWC	Since Zonal Offices have complete information about the manufacturing units and they are conducting periodical inspections, DDCs may be delegated the power to issue Written Confirmations. Initially, such powers may be delegated in cases of Renewals. This would reduce the delays and helps the export business.
		Number of Batches & Batch Size for Phase 1 Clinical trials of NCEs -At present, : 3 batches (min. 2 pilot scale) are required (NDCT)	Increased timeline and imposes an unnecessary material burden without enhancing clinical safety.	Since the primary objective of Phase I trial is evaluating safety and tolerability rather than establishing commerical manufacturing consisetency, suggeted for acceptance of one representative batch manufactured under phase-appropriate cGMP. This will harmonise practices with Global players for Phase 1 / 2 clinical trials of NCEs. Global (FDA/EMA): Single representative batch (lab/small scale) is acceptable; focus is on clinical batch quality, not commercial consistency.
		Process Validation For Phase1 / 2 filings: At present formal process validation and master formulas are required for NDCTs	For Phase I/II clinical-stage materials, locking the manufacturing process too early can stifle process optimization, while increasing the development burden, cost, and overall timeline	Industry requests to grant exemption from formal process validation for Phase 1/2 as locking a process early stifles optimization. Safety is guaranteed by a robust QMS, strict IPCs, and comprehensive end-product testing followed by manufacturing of clinical trial IMP in GMP compliance. US FDA/EMA exempt from formal validation. Detailed process description with robust in-process controls (IPCs) is sufficient.
		Analytical Method Validation for Phase I/II Filings – Full formal validation of analytical methods is currently required for NDCT applications	At the Phase I/II stage, manufacturing processes are still evolving, and methods established early in development may become obsolete as the process undergoes iterative optimization.	It is suggested for acceptance of “Scientifically Sound and Fit-for-Purpose” Analytical Method Data This would allow appropriate method development and optimization to continue as the product and manufacturing process evolve, while maintaining adequate assurance of data quality and reliability

2	Clinical Trials	Impurity Specifications at Early Stage - NDCT - Requires comprehensive monograph specifications covering the identification and/or quantification of impurities, without providing sufficient flexibility or a clear scientific framework for establishing appropriate impurity limits at the early clinical development stage.”	Requiring extensive development to establish and maintain a defined impurity fingerprint at the Phase I/II clinical stage can impose a disproportionate development burden, resulting in increased development timelines and costs without a commensurate improvement in patient safety. At this stage, both the Drug Substance (DS) and Drug Product (DP) manufacturing processes are still evolving and are expected to undergo changes as clinical development progresses, process understanding improves, and manufacturing scales increase. Consequently, impurity profiles may also evolve with process and scale changes.	It is suggested that Phase I/II clinical-stage materials, impurity acceptance criteria should initially be established based on the impurity levels observed in toxicological batches, with subsequent refinement and alignment based on data generated from clinical batches and ongoing process development. Rationale: This approach is consistent with the risk-based principles applied by major global regulatory agencies, including the FDA and EMA, for early-phase clinical development. The impurity profile of the Drug Substance used in pivotal non-clinical safety studies provides an important safety qualification benchmark. Accordingly, using the impurity levels observed in toxicological batches as the initial basis for acceptance criteria provides a scientifically justified and safety-based approach for early clinical trials.
		CT 10/12/13 applications for mfg. of BE/CT batches at Zonal offices	Delay in processing of due to document requirements (BE NOC, Protocol, clinical site and EC details) and requirements varies from zonal office to zonal office	Industry requests not t to make the submission of BE NOC, protocol, clinical site details, and the details of EC mandatory prerequisites for granting approval at the early development stage. Instead, approval may be granted with a condition requiring submission of these documents before initiation of the relevant study or clinical activity.
		Requirement of 3 months stability data of GMP batch for notification procedure for BE NOC’s for Export	Though the Notification procedure is a welcome move however requirement of 3 months stability data of GMP batch is resulting in delay in execution of project and situation is same as it was during the approval process	Industry requests that the requirement for prior availability of three months’ stability data at the time of notification for BE NOC may kindly be reconsidered. The stability data may be permitted to be submitted retrospectively, but prior to initiation of the BE study.
3	Destroy/discard of exhbit batches	As per the current practice, Indian regulations do not allow commercialization of Process validation batches manufactured under Test license in Form 29 after receipt of product permission/ manufacturing license	This restriction can result in wastage of commercially usable material and imposes an additional manufacturing and validation burden on the industry, particularly when the process validation batches have been manufactured under GMP conditions and conform to the approved quality specifications.	Industry requests for permitting process validation batches manufactured under a Test Licence in Form 29 to be released for commercial use after receipt of new drug approval/product permission from CDSCO, subject to compliance with applicable GMP, quality, and release requirements. Justification: Allowing such batches to be commercially released would facilitate earlier availability of the approved product to patients, while avoiding unnecessary wastage of batches manufactured as part of the process validation exercise. Similar regulatory mechanisms are available within European regulatory frameworks.

4	Delays in getting Form 28 D / 28 DA licences	Applicants apply to State FDA and CDSCO Zone; State FDA grants the manufacturing License then it goes to DCGI for countersignature	Significant time taken for issuing Form 28D/DA by state FDAs. Additional 2-3 months for countersignature by CLA. In some cases, joint inspection is also done before grant of Form 28D/DA/Endorsement. NOC obtained for exports is given only for one year and substaintal time is lapsed, before the licence is received.	As recommendations for granting license are issued by both state and CLA after joint inspection, License issuing authority may be delegated to state FDAs for granting the final manufacturing permission
5	Regulatory process for imported products	It involves 3 steps NDA filing in CT 18 Registration Certificate (RC) in Form 41 Import License in Form 10 - New notification dt. 26 Feb 2020 allows parallel filing of NDA & RC but RC approval requires NDA approval copy. Form 10 can only be applied once RC approval is in place.	Three steps process is time consuming as CMC documents are reviewed repeatedly in two applications (CT-18 and Form 41) and also repeat testing of product samples at IPC/CDTL	Replacing the existing 3 application forms with a single form for submission of application and approval for new drug may be considered. Two step testing requirement at NDA and RC may also be relooked. This helps s to launch the innovative new products in India within minimal time.
6	ONDLS	WHO GMP / CoPPs	Subsequent to the interactive meeting at Hyderabad with C-DAC and CDSCO team, most of the issues are resolved. However Industry expresses that some issues particularly with respect to Form 28 D licenses still persists.	Request for looking into the issues raised by the invidivual companies