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FICCI Recommendations on

REGULATORY REFORMS FOR PHARMA SECTOR IN INDIA



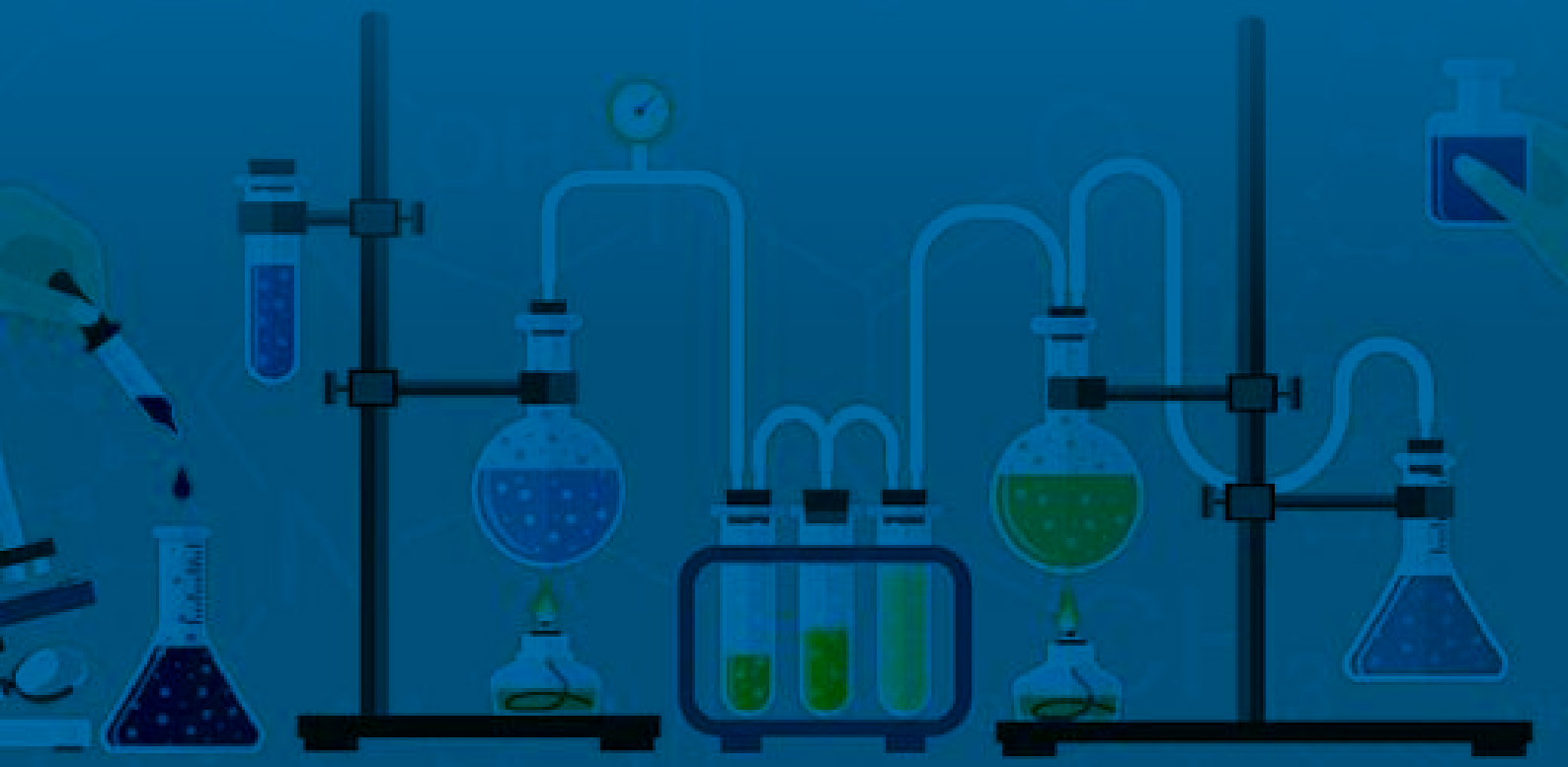
TABLE OF CONTENTS

(A) New Drug Registration: Improvement proposals 1

(B) Animal Toxicity and Testing 15

(C) Clinical Trials Related 33

(D) Shaping the R&D Ecosystem for Indian Pharma Sector (Infrastructure and Capacity Building) 43



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A

NEW DRUG REGISTRATION: IMPROVEMENT PROPOSALS



(A) New Drug Registration: Improvement proposals

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
New Drug application (NDA) – products where key country approval is available, Firm submits the dossier to HA, SEC meeting is conducted, HA approval is granted after review by SEC. **Current approval timeline for NDA is 6-9 months**	India files NDA only after such proposals are approved by key country e.g. US, EMA, Canada, Switzerland, Australia, Japan that follow a very stringent review & approval process. The proposal undergoes SEC review, which is time-consuming with some meetings being scheduled ~4 months after submission even for orphan drugs or where unmet medical need exists. Currently, no prioritization is given for orphan drugs which as per New Drugs & Clinical Trials Rules 2019 can be granted expedited review and an accelerated approval. Outcomes are not predictable	**New Drug applications which are already approved by one of the key countries (Approvals granted through stricter review - US, EMA, Canada, Switzerland, Australia, Japan), the approval should be granted by CDSCO without going to SEC.** Any query by regulators (CMC/local data related) should be issued within 15 calendar days of dossier submission. If required on need basis a F2F/virtual meeting can be scheduled at the discretion of CDSCO office. **Approval time 3 months** Increase efficiency of regulatory processes	Aim of this proposal is to reduce the approval timelines considerably to ensure early access of novel treatments to Indian patients. NDA's are mostly filed for newer or better treatment options over existing therapies and hence this proposal is aimed at having early access of Indian patients to such drugs which will support Indian government's goals i.e. **Bring innovation to India faster and ease of doing business in India.** In many countries (Malaysia, Singapore), "Reliance pathway" is followed where HA submission is done parallel to key country. Approval is granted in one month from key country approval.	**High**
Registration process for imported products, registration process involves 3 sequential filings – NDA (6-8 months),	Documentation is predominantly the same in all 3 applications (NDA, RC, IL), which involves unnecessary efforts	Single Window system – replace the existing 3 application forms with a single form for submission of application	Aim is to launch the innovative new products in India within minimal time i.e. not more than 3 months from the key	**High**

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
Registration Certificate (7-9months), Import License (1 month) **Total of 15 – 18 months** New notification dt. 26 Feb 2020 allows parallel filing of these 3 applications, but implementation and success is yet to be seen.	for the applicant to upload the same documents at different times as well for regulators to review the same documents at different time points. CTD requirement under NDA and RC filing stage is not currently aligned to ICH CTD format, need exists for harmonization to ICH CTD for ease of filing for industry and regulators review. Multiple regulatory applications and approvals for a single product permission requiring a long time.	containing product (non-clinical, clinical, efficacy, safety), manufacturing site & import details so that permission for import & marketing issued is also a single license. **New Drug applications which are already approved by one of the key countries (US, EMA, Canada, Switzerland, Australia, Japan), the approval should be granted by CDSCO without going to SEC.** **Approval time 3 months (RC and IL is part of NDA)** Any query by regulators should be issued within 15 days of dossier submission. If required on need basis a F2F/virtual meeting can be scheduled at the discretion of CDSCO office.	country approval. The theme of this proposal is Science based, Care of patients and importantly Government initiative of **"Ease of Doing Business"** and **"Bringing innovation to India".** In many countries, Reliance pathway is followed where the HA relies on the major market approval. **Moto: Bringing Innovation to India faster and ease of business** Increase efficiency of regulatory processes We should also aim at harmonization of Indian regulations for drugs with the following standards: ■ Harmonize Indian regulations for drugs with the Indian regulation for Medical devices which is a single step (IL only) approval process in India.	

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
Additional indication, New claims* & Post Approval Changes - products where key country approval is available, Firm submits the dossier to HA, SEC meeting is conducted, HA approval is granted after reviewed by SEC. **Current approval timeline just for NDA is 6-9 months** *new claims – new dosage form, new strength, new presentation, new route of administration, change in label, Package insert update, change in pack size, etc.	Firms files for Additional indication, new claims or Post approval changes only after such proposals are approved by key country e.g. US, EMA, Canada, Switzerland, Australia, Japan that follow a very stringent review & approval process. The proposal undergoes SEC review, which is time-consuming. Currently, no prioritization is given for orphan drugs which as per New Drugs & Clinical Trials Rules 2019 can be granted expedited review and an accelerated approval. Outcomes are not predictable, SEC committee requirements Variation Management process is poorly defined.	**Additional indication, new claims or Post approval changes applications which are already approved by one of the key country (Approvals granted through stricter review - US, EMA, Canada, Switzerland, Australia, Japan), the approval should be granted by CDSCO without going to SEC.** Any query by regulators (CMC/local data related) should be issued within 15 calendar days of dossier submission. If required on need basis a F2F/virtual meeting can be scheduled at the discretion of CDSCO office. **Approval time 3 months Increase efficiency of regulatory processes** Define a harmonized process for variation management for chemical and biological entities	Aim of this proposal is to reduce the approval timelines considerably to ensure early access of novel treatments to Indian patients. For imported products additional indications / new strengths are mostly filed for newer or better treatment options over existing therapies and hence this proposal is aimed at having early access of Indian patients to such drugs which will support Indian government's goals i.e. **Bring innovation to India faster** and **ease of doing business in India.** In many countries, Reliance pathway is followed where the HA relies on the major market (US, EMA, Canada, Switzerland, Australia, Japan) approval.	**High**
Requirement for Local data either GCT / Phase III / Phase IV	• Delay in launch of medicines for unmet medical	No Local data generation if the new drug is approved in	Based on concept of ICH E5 and E17 guideline.	**High**

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
study	need leading to drugs reaching patients after a long delay • Duplication of clinical data and resources in India	an ICH territory and there is low risk anticipated due to ethnic difference (ICH E5 and E17) Strengthening Pharmaco-vigilance system can help to mitigate the potential low risk of ethnic difference. Enhance the clinical research environment in India to attract more global pivotal studies such as fast track review of Global pivotal studies.	Although ethnic differences among populations may cause differences in a medicine's safety, efficacy, dosage or dose regimen, many medicines have comparable characteristics and effects across regions. ICH E5 describes regulatory strategies that minimize duplication of clinical data and facilitate acceptance of foreign clinical data in the new region Current system requiring local data is not in line with ICH recommendation. Allows launch of drug in India as part of first wave countries globally thereby benefitting Indian patients **Increase efficiency of regulatory processes, Reduce unnecessary burden on firm**	
Currently there is nothing like fast track, breakthrough review or orphan drug review	All proposals are having same pathway. Indian patients don't get access of essential drugs	Proposed new review process for New Drug, Additional indications & New Claim	▪ Rationale approach for considering several proposals that come to DCGI office	**High**

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
In the New Drugs and CT rules published in March 2019 – accelerated pathway is mentioned, however the same is not implemented 100%		**1) Regular** a) Regular (Approval timeline 6 months, SEC review yes) b) Regular with Reliance pathway (Approval time 3 months, SEC review not required) **2) Unmet need / Rare disease** a) Priority (Approval timeline 3 months, SEC review yes) b) Priority with Reliance (Approval timeline 1 month, SEC review not required) Accelerated pathway should be implemented with clear benefit in timeline	▪ Global regulatory pathways for ex. of US FDA, EMA etc. wherein multiple pathway are available. ▪ Adopt Reliance pathway in India, which considers the review of key countries and clears the innovative drugs in a very short time which many countries in South Asia and Latin America are adopting	
Conducting SEC through virtual meeting	Currently, a physical presence is required. In the wake of the ongoing COVID-19	Conduct SECs through virtual meeting.	Attending SEC through virtual meeting will eliminate the need of physical presence.	**High**

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
	crisis, physical presence and also travel for people from different cities is currently prohibited and may be restricted in the future.		This will also help in furthering the Indian Government's vision of increasing the adoption of digital technology.	
Currently package insert is in the carton is in hard copy	Dynamic changes not possible and Change is cumbersome process, slower process	Dynamic digital labelling (E-leaflet / package insert) should be adopted	Dynamic changes can be implemented and faster compliances. It will also save paper	**Medium**
Custom Duty 10% and GST 12% = Total 22%	There is high custom duty and GST on the novel imported products. Some of these products are used for unmet need and rare disease	Waive the Custom duty and GST for following imported products which are approved globally and come under following criteria: ▪ Life threatening ▪ Serious diseases ▪ Diseases of special relevance to Indian health scenario ▪ Unmet need ▪ rare diseases / orphan drug, ▪ No drug is available ▪ Pandemic / Emergency	Aim of this proposal is to ensure early access of novel treatments to Indian patients and pass on the benefit of 12% (custom duty and GST saving) to Indian patient.	**High**
Challenges with online SUGAM system	Online SUGAM portal has several challenges and errors.	**Online portal should be very user friendly with no errors.** Key countries such as US,	There are several resources of advanced Information Technology (IT)	**Medium**

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
	There are no provisions for online submissions in SUGAM for few submissions e.g., SAEs, Biological post approval changes variations and needs hard copy submissions.	EU has an excellent software system with ease of working. **All submissions should be on the online portal.** This is of paramount importance especially in such times of COVID. Submission dossier format should be aligned to global standards. Eg. Common Technical Document	available in India and can be utilized for advanced IT technology in India. This will support "ease of doing business: in India.	
Transparency on Market Authorization CDSCO publishes the approval on CDSCO website. However, there is status update of submission of application/ review of application till approval is granted However, there are many drugs approved by central HA/ CDSCO are not published or information on approval is made available after delay.	In the current SUGAM portal system, all information in respect of market authorization for a drug substance/drug product (new or otherwise) information is only available to the applicant and CDSCO/State or UT FDA's. The innovator company only comes to know after the drug enters market	Government should have a mechanism whereby the drug approved by Central HA/ CDSCO in India, shall be made available immediately on the CDSCO website in a transparent manner. SUGAM portal should notify the status of marketing application/s and approval thereof that provides name of the applicant, drug, dosage, formulation etc.	This will bring more transparency on regulatory approval system in India and build more confidence amongst all stakeholders.	**Medium**

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
Biosimilar Product Approval Process				
RGCM - Approvals Sponsor has to take permissions to import/export of GMO/Clones/carry out R&D etc. Sponsor has to seek approval for conducting the Toxicity protocol approval and also Toxicity report approval	A lot of time (few months) goes in receiving these approvals. All these approvals act as a hindrance for start up's as well as for drug development. At a very initial phase of drug development this level of scrutiny is not required. The data available at this stage of development is also not relevant decide the fate of the product	All such information shall be notified by the firm on an annual basis to the central drug regulator. Central drug regulator will have a direct control over all such activities. **(Single window clearance)** Animal studies for Biosimilars should be waived off in line with what ICH countries like U.S & EU OR Toxicity data shall be reviewed at the time of issuing NOC to conduct human clinical trial by DCGI. Product specific guideline for non-clinical expectation for each molecule should be specified	No such approvals are required anywhere else globally. For Generics product also DCGI reviews the pharmacology and toxicology data during the clinical trial application review. Clarity of non-clinical development. EMA provides product specific guidance. U.S & EU provides waiver for Toxicological studies and firms get an opportunity to present the Analytical similarity data and obtain waivers for Toxicological studies based on the grounds that "Animal models do not reflect toxicological properties of drugs in humans" Can help align with global standards	**Medium**
SEC Provides approval to conduct clinical studies	Protocols approved by EMA / FDA thru scientific advice are cross questioned.	RCGM, SEC, DCGI – all approvals need to come under single window.	Biosimilars can be developed at a lower cost if clinical studies can be done quickly in India.	**High**

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
	No clarity of approach to evaluate new formulations or new dosage forms	Guidelines for SEC presentation, importance of similarity data to be given.	Provide guidance to accept the formal scientific advice from agencies like EMA and FDA	
Manufacturing Licenses Form 29 license is required during development and manufacturing clinical batches	A lot of time (few months) goes in receiving this approval. All these approvals act as a hindrance for start up's as well as drug development	No Form 29 shall be required for the developmental and toxicity batches. Firm shall submit all the manufacturing site details where the CT batches will be prepared in the CT application. CT permission will also include where the CT material will be produced	No such approvals are required anywhere else globally.	**Medium**
PK-PD Studies Variations in Permission to conduct PK/PD and Phase III human clinical trial Different companies have different sample size allocation for the same product	No clarity leading to confusion	Product specific guideline for clinical expectation for each molecule should be specified.	Clarity of clinical development. EMA provides product specific guidance.	**Medium**
Post Approval Study Requirements Permission to conduct Phase IV studies There is no clear guideline about number of subjects, safety or efficacy	Lack of defined process or a guideline gives a perception of discretionary and arbitrary approach besides confusion.	Clear guidelines or guiding principles for Phase IV and Post marketing studies to be provided. Come up with at least product class specific guidance	EMA provides product specific guidance.	**Medium**

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
being primary criteria, confusing nomenclatures for PMS (post marketing study or surveillance), Further, the guidelines are not clear if the study should be done in one indication or all the approved indications				
Drug Import Permission Permission to import the drug for conduct for Bio-similarity has limited validity.	Repeat applications to be made leading to inefficiency	Validity should be increased to 5 years and Quantity should be allowed enough to do Analytical Similarity as well as Non-clinical similarity	Savings of Time and efforts for both Regulators and Firm	**Medium**
Form 28D Applicants apply to State FDA, State FDA grants the License then it goes to DCGI for countersignature	Time taken in issuance of Form 28D for start of manufacturing of an approved drug is usually 6 to 8 months- significant delays in development	Form 28D application shall be done in parallel to state FDA while applying for marketing approval to central drug regulator and it should be issued or approved on the same time as and when drug is approved by the central drug regulator. So that the Sponsor can start manufacturing just after receiving the marketing authorization	It will save a lot of time (6 to 8 months) for the new drug to be available to patients after receiving all the approvals.	**High**

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
DCGI/CDSCO zonal office/DCA/RCGM NOC's complex process Manufacturing and Test licenses are provided by DCA, RMP import permissions, special permissions are provided by Zonal offices, Inspections are jointly conducted by DCGI, Zonal and DCA. Import/Export/Tox studies permissions are provided by RCGM	Involvement of Multiple agencies is delaying the drug development and approval of the product as companies have to liaise with multiple offices at all times to facilitate cross office communications (at few places) and also to ensure receipt of quick approvals. Most of the time, inspections report closures are delayed due to unavailability of all relevant stakeholders at a specified time and also causing delays during review of CAPA's. There are multiple challans needed by different offices for different applications	There should be single window to process for all licenses/permissions. There should be single Annual payment fee announced for each molecule in development and this fees should be charged annually, thereby ruling out the need for separate challans for individual applications. Only critical applications such as marketing authorisation and clinical trials applications can have an additional fee payment structure.	So much of time gets elapsed by co-ordinating with multiple offices in India. Further, lack of adequate resources in these multiple offices also causes delay as not all of the relevant officers may be available at one time to conduct joint inspections.	**High**

B

ANIMAL TOXICITY AND TESTING



(B) Animal Toxicity and Testing

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
Requirement of approval from Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) for conducting all large animal studies including Beagle dogs, monkeys, minipigs etc. within India	Delay in drug development programs because of the meeting schedules of the committee - time required to get the approval to conduct large animal studies in India is nearly 4 months.	• Empower IAEC (like in US) to review and approve the large animal protocols, as anyway IAEC has 4 members nominated by CPCSEA OR minimize the duration of approval process (to 2-weeks). • Lay down rules and regulations on large animal use, with emphasis on action for defaulter Institution.	• Large animal testing (non-rodents) is a regulatory requirement for approval of drugs. • Small molecules (NCEs or new chemical entities) require non-rodent Toxicology study in one of dog or monkey species • Majority of large molecules (NBEs or new biological entities, i.e., novel Biologics or Biosimilars) require testing in monkeys • Delays adversely affect filing of drug applications	**High**
• Requirement of approval from central Review Committee on Genetic Manipulation (RCGM) before initiating toxicology studies for Biotechnology-derived (New Biologics or Biosimilars)	• Delays in drug development program due to time required to get approval from RCGM, an unnecessary step that is not required and followed in any other countries (e.g., USA, UK, Canada, Germany	• Empower Institutional Biosafety Committee (IBSC), which has external RCGM GOI appointed members, to review and approve such proposals.	• Central RCGM review is an unnecessary step in the entire process of approval of toxicology testing for Biologics materials which is not followed in other countries.	**High**

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
materials for India registration.	etc). This time is in addition to IBSC and IAEC approval requirement. All study proposals and results need to be reviewed by RCGM – delays. Creates delays in competitive biologics / biosimilars field	• If necessary, add couple of subject matter external expert (Govt. of India nominated) within IBSC to further scrutinize the proposals.	• Delays adversely affect filing of drug applications	
• Lack of supply of large animals (dogs, monkeys, minipigs etc.) for conduct of studies in India • Process to import dogs for regulatory studies within India is cumbersome • No permission to import monkeys • Lack of breeding facility of minipigs • Challenges also in importation of rabbits • Requirement of Convention on International Trade in Endangered Species (CITES) permission to import monkey plasma.	• Very limited source for Beagle dogs (only one vendor). • No centralized breeding and supply of dog facility in India. • Very few airlines carry dogs into India • No Indian commercial supplier and no procedure for import for Cynomolgus monkeys • No commercial organization that can conduct monkey toxicology studies in India.	• The import of large animals for experimentation can be facilitated. • Alternately, a central breeding centre or private organization for dogs, monkeys and minipigs can be established. • A clear process of CITES permit issuance should be established.	Critical time and money can be saved by either: • Through establishment of central breeding facility for dogs, monkeys and minipigs • Making it easier to import	**High**

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
	• Time-consuming import processes, and inadequate suppliers of animals result in outsourcing regulatory tox studies in dogs and monkeys to countries abroad • No clarity on authorities issuing CITES permission to import monkey plasma to India. • Specific Indian test requirements for rabbit importation are not performed by international vendors			
• Import of transgenic mice, specific strains of rats/mice, rabbits etc. require submission of experimental protocol to IAEC and then seeking import permit • Mandatory quarantine of lab-grade large animals, including rabbits and dogs intended for research in Govt quarantine facilities.	• Time for DGFT to review the import application, dependency on overseas laboratories for animal procurement, payment of ~30% import duty, transportation cost etc. • Cumbersome quarantine requirement - Institute scientists go the quarantine lab at port of entry to help in the process	• A single-window, fast-track clearance can be created for import of genetically modified organisms such as transgenic mice and other animals used in research. • Waiver of mandatory quarantine of large animals in Govt Quarantine facilities. Institute testing facilities are routine	Aim of this proposal is to reduce the approval timelines considerably to ensure early access of novel treatments to Indian patients. NDA's are mostly filed for newer or better treatment options over existing therapies and hence this proposal is aimed at having early access of Indian patients	**High**

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
		monitored, should be adequate for quarantine. • Establishment national labs that can sell these specialized animals to industry OR • Attract overseas well-known animal breeders to India (e.g., Jackson Laboratories – non-profit organization) OR ease the process of import. • Simplification of processes for import of some research materials like specialized animal diets for research in animal models, research kits and biological samples with short expiry date.		
No process on regulatory feedback before the Investigational New Drugs (IND) or New Drug Application (NDA) submission (e.g., pre-IND meeting, Type A or C meetings) or Carcinogenicity Assessment Committee (CAC)	Sponsors/companies are dependent on US FDA or other regulatory authorities for critical input on testing requirement that are important for human safety.	• Create team dedicated, trained reviewers at our FDA, similar to the practice at USFDA/ EMEA etc. Cost can be offset through filing fees. • Augment training for reviewers	• Human safety is pivotal aspect of the clinical trial. A Sponsor will not have database to know variety of safety issues encountered by other Sponsors. Regulatory authorities are	**High**

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
		• Obtain consultation with overseas expertise from other government regulatory bodies	common for all Sponsors so they can build and get access to such databases. • Regulatory authorities in India should create a repository/ database of studies that can inform on human safety • Regulatory authority should direct the Sponsor to fulfil certain requirements before submission of IND or NDA.	
Lack of guidelines on toxicology requirement for biotechnology derived materials development (e.g., new large molecule drugs)	Large molecules development need a different approach as compared to small molecules, primarily use of monkeys as cross reactive species.	Co-opt the ICH guidelines on large molecules toxicology testing, commonly done in other countries.	Many companies are working on novel large molecule discovery to treat various unmet medical need. Hence, they need direction on regulatory requirement from India.	**Medium**

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
Lack of guidelines on toxicology requirement for disproportionate metabolite qualification for human safety	Metabolites could potentially cause safety concerns in human	Co-opt the FDA guidance on metabolite safety testing in animals	To support the safety testing of metabolites of new drugs of human during clinical trial.	**Medium**
Lack of guidelines on toxicology studies in Juvenile animals to support Paediatric use of drugs	Dependency on International guideline.	Co-opt the ICH guidelines, and thus make them applicable for India as practised in other countries.	To support the safety of new drugs use in Paediatric population.	**Medium**
No requirement of human Absorption, Metabolism, Elimination (AME) radiolabelled studies for evaluating parent or metabolites profile	Without human AME's studies, drug development is incomplete.	Develop a guideline on human AME studies and infrastructure to facilitate radiolabelling facilities.	Required to assess the safety of human in clinical trial and understanding of fate of drugs when consumed.	**Medium**
No clarity on toxicology requirement for fixed dose combination.	Safety in human with new fixed dose combination products.	• Co-opt the ICH guidelines, and thus make them applicable for India. Done in other countries If both the products are approved in the country, a toxicity study with combination product of 90 days	Clarity or direction is required for companies to develop fixed dose combination drugs.	**High**

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
		maximum duration (for chronic use) in one relevant species is considered appropriate for to support the long term Phase III trial and marketing authorization (US FDA, ICH, EU and ANVISA guideline on FDC).		
Requirement of 4-week toxicology studies in rodents and non-rodents for first time registration for the drug already approved in other countries.	Unnecessary use of animals, expenses, and lost time for the organization even though the API specification meets the ICH specification.	For drugs approved in ICH country and complete data is available in public domain (e.g., Freedom of Information Act, Summary basis for approval).	If the Sponsor's data meets inventor's specification, and FOI information on safety is submitted to regulatory authorities, conducting additional studies in animals would prolong time to bring the drug in to market, create unnecessary expenditure on animal studies, and required excess use of animals etc.	**High**

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
Lack of guidelines on impurity qualification in drug substance, drug products and elemental impurities.	Safety concerns in human	Co-opt the ICH guidelines, and thus make them applicable for India. Done in other countries	Would improve the safety testing procedure in India, and prevent health hazard from drugs that may contain unsafe levels of unknown or toxic impurities.	**Medium**
Limited scope to access central labs/infrastructure or library or national expertise.	For a small organization, investments on advanced instruments, accessing literature etc is an issue.	Create one or more central nodes/facilitators on existing national expertise and infrastructure with a digital presence can provide access to specialized instrumentation, technologies and expertise within CSIR labs, other national institutions and universities. This could optimize utilization of these national resources, and importantly encourage communication and collaboration. • Create library along the lines of the National Library of Medicine (NLM, USA)	Would provide support to small organizations, avoids unnecessary expenditure if the facility is existing within the same/neighbouring cities. Also, would reduce expenses on getting literature from overseas library or publishers.	**Medium**

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
• Dependency on import for reagents, kits, animal feed, • No central agency for pathogen-free mammalian cell lines similar to American Type Culture Collection (ATCC) for cell derived (CDX) xenograft studies of anticancer compounds • No patient-derived Xenograft (PDX) Banks for animal testing in oncology. • No well-curated Tissue Banks	• Time required for such procurement, shipment lost, additional cost for customs. • CDX and PDX studies in animal models are the basis of new anticancer drug discovery and development. Currently there is very limited access and a lot of time and money is spent to source these materials	• Create National Repository to bank, safe deposit and supply well characterized, pathogen-free mammalian cell lines similar to the ATCC (American Type Culture Collection) in the US, or RIKEN (Institute of Physical and Chemical Research) in Japan. • Create PDX banks, complete with individual's medical history • Create a suitable local vendor ecosystem by easing norms for maintenance and supply of research material including consumables, reagents, cell-lines etc.	• Easy availability of cell lines will save time, cost and hasten the drug development process. • CDXs are critical for preclinical oncology studies of new anticancer agents in genetically well characterized cancers isolated from patients. • PDXs are critical for preclinical oncology studies of new anticancer agents in genetically well characterized cancers isolated from patients. • Tissue samples from various organs of the same patient can enable study of tissue pathology, and also be used to study the DNA variations in the same samples. Such an effort will be very useful to identify biomarkers of disease.	**High**

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
Limited talent pool in the industry especially on large animal toxicology testing (dogs, monkeys, minipigs)	• Interpretation of critical data, standardization of certain experiments/parameters in the toxicology studies.	• Hiring talent pool- Indian origin scientists/ researchers in foreign countries	• To improve the current standard of toxicology testing and interpretation.	**Medium**
New Clinical Trial Rules. 2019: Toxicology; Part II- Section 3 (i) page 198-199 of Schedule states for Phase II clinical Trial: • Repeat dose systemic toxicity studies of appropriate duration to support the duration of proposes human exposure' • "Segment II reproductive or developmental toxicity study (if female patients of child bearing age are going to be involved)'	• Cumbersome rules to follow for enrolling female cancer patients for the trial. • Slow enrolment of patients if the stringent criteria has to be adopted. • Delay in clinical efficacy evaluation of a potential treatment option for advanced cancer patients	• Duration of the final systemic toxicity study will depend on the duration, therapeutic indication and scale of the proposed clinical trial. For clinical trials in advanced cancer (oncology) patients, 28-day toxicology studies with recovery phase should suffice • Phase II Clinical Trials require Segment II reproductive or developmental toxicity study (if female patients of child bearing age are going to be involved) **or adequate contraceptive measures be taken.**	To align with ICH S9 (**Guidance for non-clinical evaluation of anticancer pharmaceuticals**) guideline: • The non-clinical data to support Phase 1 and the clinical Phase 1 data would normally be sufficient for moving to Phase 2 and into second- or first-line therapy in patients with advanced cancer.	**High**

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
Schedule Y Drugs and Cosmetics (IInd Amendment) Rules, 2005 guideline related				
Following regulations of toxicology testing for small molecules are not in line with International guidelines (e.g., International Committee for Harmonization, ICH), which requires Companies to conduct some of the toxicology studies twice or Combine both Schedule Y and ICH guidelines design in the same study which is complex, expensive and require additional animals use. Preclinical requirements for IND can be harmonized with internationally recognized guidelines such as those of OECD, ICH, USFDA, EMEA, etc. to avoid unnecessary repetition of studies and to expedite IND/clinical development.				
Genotoxicity testing: The following standard test battery is generally expected to be conducted: • A test for gene mutation in bacteria. • An in vitro test with cytogenetic evaluation of chromosomal damage with mammalian cells or an in vitro mouse lymphoma TK assay. • An in vivo test for chromosomal damage using rodent hematopoietic cells.	• Recent advances in genetic toxicity testing can reduce animal usage and still provide the necessary information for an assessment of the genotoxic potential of substances	• Create guideline that allows integration of the cytogenetic tests into repeated dose toxicity studies. This can be used to satisfy the in vivo cytogenetic data requirement. Hence there would be no need to use separate animals for in vivo micronucleus or chromosomal aberration test.	• Integration of a cytogenetic assay into repeat-dose toxicology studies is technically feasible and is a scientifically acceptable alternative to conducting independent in vivo cytogenetic assays such as bone marrow micronucleus test in rodents. • Also, it is internationally accepted by various agencies including the ICH for pharmaceuticals.	**High**

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
Acute toxicity testing: • Need to acute toxicity study in two rodent species	• Not a requirement by ICH or other regulatory agencies. • Poor utility of the data at least till Phase 2 of drug development.	• Remove requirement of acute testing in two rodent species OR can make it mandatory before marketing authorization as the data will be useful for deriving health based risk assessment for people working in manufacturing plants.	• Poor scientific rationale • Reduces animal use (3Rs principle) • Saves time • Information on acute toxicity can be obtained from appropriately conducted dose-escalation studies or short-duration dose-ranging studies that define an MTD in the general toxicity test species, hence such studies are not essential before Phase I or II.	**High**
Repeat dose toxicology studies				**Impact (High, Medium, Low)**
Animals per testing group In a 90-day toxicology study: Number of animals to be tested as follows: For rodent studies, number of animals stipulated is 15 to 30/sex/group including recovery of control and high dose treated groups.	• Two sets of animals in treated and control reversal groups to be sacrificed within a span of 14 days treatment free period will not add any scientific value but will unnecessarily increase the number of animals in the study.	For recovery group, sacrifice only once at 28 days after stopping treatment. Thus, reduce the number of animals for the reversal group: • In a 90-day toxicology study to:	• India is a signatory country to the OECD for Tox testing and Mutual acceptance of data. • Should comply with ethical usage of animals in the toxicity studies.	**High**

Repeat dose toxicology studies				Impact (High, Medium, Low)
For the recovery groups, half the animals in "reversal" groups (treated and control) should be sacrificed 14 days after stopping the treatment. The remaining animals should be sacrificed 28 days after stopping the treatment or after the recovery of signs and/or clinical pathological changes- whichever comes later, and evaluated for the parameters used for the main study. Similarly, number of animals in 180-day toxicology study: One rodent (15-30/sex/group) and one non-rodent (4-6/sex/group) species are needed	• No scientific rationale to use these many animals. Not aligned with International guideline.	Rodents: 10/sex/group Non-rodents: 3/sex/group • In 180-day toxicology study: Rodents: 12/sex/group Non-rodents: 4/sex/group	• The proposed animal number would allow scientific interpretation of the study result with no compromise on additional animal requirement. • This will save cost, reduce animal usage and ensure that we are in-line with international norms.	
Carcinogenicity studies: Requirement for Carcinogenicity study prior to Phase III when there is a cause for concern, or when	• Duration of dosing in Carcinogenicity testing in rats is about 2 years, plus an additional 10 months to complete data assessment and get the report.	Carcinogenicity studies in rats and mice (transgenic mice) should be required before marketing approval, not before Phase III.	• It is practically impossible to conduct Carcinogenicity studies before Phase III. • The proposal is in-line with ICH M3R2 and S1A guidelines	**High**

Repeat dose toxicology studies				Impact (High, Medium, Low)
the drug is to be used for more than 6 months.	Doses for Phase III need to be selected based on Phase II result. • Also, cost for conducting carcinogenicity study in rat would be ~7 Cr INR (Indian CRO). Additional ~5 Cr INR for conducting carcinogenicity study in transgenic mice. Hence, carcinogencity data submission before Phase 3 is practically challenging for any industry. • It is also contradictory to Schedule Y recommendation on clinical trial of >24 weeks, requires 24 week (6 month) rodent and 36 week (9 month) non-rodent studies for marketing approval.			

Repeat dose toxicology studies				Impact (High, Medium, Low)
Peri-postnatal (Segment III) study Experimental design is very different from the International guideline	Overseas company may need to conduct studies as per Schedule Y design of this study OR our studies conducted as per Schedule Y will not be acceptable to worldwide.	Harmonize the study design with ICH or EMA guideline.	ICH and EMA guidelines are comprehensive and universally accepted. Aligning our guideline with ICH would reduce the animal use, unnecessary expenditure, time etc.	**High**

C

CLINICAL TRIALS RELATED



(C) Clinical Trials Related

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
CT Rules Current guidelines do not specify the requirements of stability data and duration for different Phase of clinical development (Phase 1, 2 or 3), and at the time of product approval/ registration.	Ambiguity and discretionary practices prevail leading to delays	The guidelines should specify different requirements (duration and conditions as well as number of batches needed) for different phases of clinical trial / commercial approval. Additionally, Clinical trials phase specific analytical method validation, and process development/ validation should be specified	Harmonization with the guidelines in US/EU	Medium
CT Rules Requirement for conducting Phase I trials in India for new drug substances discovered or developed in India	Creates restriction and limitations in the developmental process especially till India builds capability for global standard Phase-1 study capabilities	While encouraging Phase I trials for for new drug substances discovered or developed in India, a Phase 1 trial done outside India should be acceptable for next phase of clinical trials since safety will also be evaluated in Phase 2 and Phase 3 trials as well.	In line with regulations of Other markets	Medium
Subject Expert / IND Committees Provides approval to conduct clinical studies. Decision	Inconsistency in decisions leading to confusion, delays and lack of confidence	Deployment of full-time trained professionals for application review and approval to	Harmonization with ICH guidelines with respect to early phase clinical trial requirements,	

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
making by vocal member and tendencies for an arbitrary review. Dependency on external part-time government only professionals many of whom have minimal research experience for application review and approval Absence of specific development area experts like statisticians, drug development experts for effective deliberations during the review	Lack of harmonization with ICH guidelines with respect to early phase clinical trial requirements Protocols approved by EMA / FDA thru scientific advice are cross questioned. No clarity of approach to evaluate new formulations or new dosage forms	ensure consistency that is science based. Considerations for local data need should be defined Inclusion of required experts for effective deliberations during the review. Relook at Government ONLY panel. Consider Ex-Industry- local or global as experts in such panels to facilitate this RCGM, SEC, DCGI – all approvals need to come under single window. Guidelines for SEC presentation, Roles and mandates of panel to be clearly defined	product approval and life cycle management Biosimilars can be developed at a lower cost if clinical studies can be done quickly in India. Provide guidance to accept the formal scientific advice from agencies like EMA and FDA	High
SEC meetings are conducted via in person physical meetings In the wake of the ongoing COVID-19 crisis, physical presence of applicants across India is challenging and may continue for many months in future thereby causing delays.	With no SEC meetings taking place, there is complete halt of review/ approvals of NDAs, GCT applications leading to unpredictable delayed approvals.	Options of e-SEC meetings should be implemented in all Therapeutic Areas through virtual meetings. This will also release the burden of people travelling from various places and limit the dependency of Delhi based members only dominating the committees.	Participate in the digital India campaign and contribute to efficiency and ease of doing business	High

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
CDSCO and State FDA Requirements Form 29 license is required during development and manufacturing of clinical batches	Sufficient amount of time upto a few months goes in receiving this approval. All these approvals becoming a hindrance for drug development where time is critical	Form 29 requirement can be done away with for the developmental and toxicity batches. Applicants can submit all the manufacturing site details where the CT batches will be prepared in the CT application. CT permission will also include where the CT material will be produced A gazette notification in this regard would be highly appreciated	No such approvals are required anywhere else globally.	Medium
Protocol Amendments For GCT needs to be submitted along with key country approval and notified/ approved. There is no defined process for submission of protocol amendments- major/ minor and whether notification /approval is needed for all clinical trials. Many a times, amendments are reviewed by SEC which leads to	Unclear pathways lead to delays in approvals of amendments and thereby studies cannot be continued affecting patient enrolment and delay in development.	Protocol amendments be defined as Major, Minor and Administrative. Major amendments should be approved in one month be it with SEC opinion or without it based on CDSCO view Minor and relevant administrative amendments can be notified to DCGI	Major amendments in GCTs if approved by key country, approval from CDSCO should be considered based on key country approval with or without SEC referral and will facilitate early implementation. This supports global harmonization. In some situations, ongoing patients' safety can be affected.	Medium

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
delayed approval and implementation as compared to other countries.				
Serious Adverse Events Currently there is no online SUGAM facility for submission of SAEs and routine submissions for old GCTs Closure/ Opinion on SAE outcome takes more than a year currently and repeat documentation sought	Physical submission/ review in paper copy of SAEs and others involves resource and time from applicant and regulators. Companies have to continue and renew their Insurance coverages for additional years till conclusion of the events. This is very inefficient on one hand but also puts the regulatory office into a bad light especially on Patient safety Issues	Facilitate e-Submission for all including SAEs and other submissions currently in paper format on SUGAM All SAEs should get closed from DCGIs point within 6 months of initial reporting	Online submission in SUGAM will save resources/ time of applicant/ regulators and speed up processing of SAE submissions and will help strengthen adherence and be harmonized also with other markets	Medium
Import of clinical trial supplies (other than investigational medicinal products) like, lab kits, devices, hand-held GSM devices, etc All electronic devices require BIS certification for custom clearance. Additionally, all GSM devices require IMEI certification from MSAI	This delays the start-up timelines of clinical trials to more than 200 days, even if DCGI approval is received within 90 days	All clinical trial supplies, including electronic items and medical devices should be exempt from additional documentation requirements.	All clinical trial supplies including electronic items and medical devices are being imported for research purpose and not for any commercial purpose or sale. The CT approval should suffice	Medium

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
Post Marketing Study Requirements Majority of Phase IV/ Observational studies are aimed to generate effectiveness data of drug in actual clinical setting. While the new CT Rules address some of these issues in writing, however such studies are rated like other Clinical Trials with all requirements of interventional studies	Restricts the ability to generate real world data on safety and outcomes associated with therapeutics Lack of expertise within the regulatory agency	Reliance on newer ways of looking at real world data/evidence (RWD/E) generation which helps to achieve the objective of monitoring drugs post marketing. With National health record structure already suggested by MoHFW, roll out of RWD/E can be easy.	Will help in generating lots of therapeutic data for the drugs in use, help us about disease outcomes and this info can be valuable for the whole drug development and regulatory echo system	Medium
Approval Timelines Approval timelines for various applications vary a lot. Timelines defined in CT Rules like 30 days and 90 days are not implemented fully. Also, no clear regulatory pathways along with timelines like routine review, accelerated/ fast track review etc	Application to approval process is unpredictable and unreliable	Approval timelines should be defined for New drugs, Clinical trials, additional indications, import registration etc Time bound approval process (like EU or US) where review happens in a fixed period of time and there is a stop clock when queries are raised.	Access to the drug has to be faster and in time-bound manner. In key countries such as US, EU, clear defined timelines exists for routine review, fast track process, accelerated review etc. Predictable, short and time bound timelines will attract the foreign companies and will also ensure timely access to Indian patients.	Medium

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
Requirement for Local data either GCT / Phase III / Phase IV study Currently there is a requirement of generating local data. While the new CT Rules do have a mention of exemption of local requirement of data generation for approval for different situations, however, in practice we do not have many examples the only exception being the current Covid -19 situation. In general, the typical old traditional way is followed.	Delay in launch of medicines for unmet medical need leading to drugs reaching patients after a long delay Duplication of clinical data and resources in India	No Local data generation if the new drug is approved in an ICH territory and there is low risk anticipated due to ethnic difference (ICH E5 and E17)	It is understood that ethnic differences among populations may cause differences in a medicine's safety, efficacy, dosage or dose regimen, but many drugs have comparable characteristics and effects across ethnicities Current system requiring local data is not in line with ICH recommendations This also helps strengthening Pharmaco-vigilance system which can help to mitigate the potential low risk of ethnic differences Increase efficiency of regulatory processes, Reduce unnecessary burden on the companies	Medium
Global Clinical Trial (GCT) applications can be submitted post approval in key country. All GCT applications are referred for SEC review and average approval timelines is about 2-3 months	India already lags behind in timelines since application for GCT is files post approval in key country. Considering competitive recruitment across countries, this leads	CDSCO to approve the GCTs based on key country approvals e.g. US. EU, Canada etc without referral of such GCTs to SEC review. Defined approval timelines of 1 mo should be	Many key countries have deemed approval process of 30 days for GCTs e.g. US and ensured faster study start.	

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
	to delayed study start in India and Indian patients are deprived of access to innovative therapies access.	followed. Any query by regulators should be issued within 15 days and approval should be granted within 15 days of response by applicant.	This proposed process will make India highly competitive for such GCTs and will enhance more global clinical research in India and access to innovative medicines for large no. of Indian patients. This process will further ensure Indian patient data supporting new drug approval and will facilitate early launch. This will also Bring **innovation to India faster and ease of business in India.**	High

D

SHAPING THE R&D ECOSYSTEM FOR INDIAN PHARMA SECTOR (INFRASTRUCTURE AND CAPACITY BUILDING)



(D) FICCI Inputs on Shaping the R&D Ecosystem for Indian Pharma Sector (Infrastructure and Capacity Building)

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
India has huge Govt supported research infrastructure (e.g. CSIR, ICMR, DBT), with each one working independent of the other and under different Ministries	• Govt research infrastructure not being leveraged to the optimal scale • Tendency to work in silos • Inadequate collaboration between public and private research efforts	• Break the silos by creating a position of "Chief Scientific Advisor", responsible to coordinate national health research policy and implementation • Rotational programs for scientists (fixed tenure of 2-3 years) between public and private sector research institutes • Bring foreign expert researchers to work in public sector institutes and send researchers from Indian institutes to foreign public sector institutes to improve ecosystem	• Optimization of research across various Govt institutes • Creating an ecosystem of collaboration and cross-learning • Enhance basic research ecosystem	High
• No incentive to do high quality basic research in academic institutes unlike abroad, where research grants are competitive and awarded only	• Set minimal basic research output from academic institutes. • Indian pharma industry is not able to benefit from any basic	• Invest in scientists by providing them the right ecosystem to stay in India or return to India • Create a National Biomedical	• High quality basic research in academic institutes • Fostering of Industry-academia partnership that can lead to better	High

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
to high quality research proposals. • Indian pharma industry often works in silo on basic drug research.	research coming out of Indian academic institutes for novel drug development.	• Research Board of external research experts (including members from academia and industry) to choose R&D projects that are likely to be impactful and to guide the teams working on these projects to execute them effectively. • Increase funding to academic institutes for basic research and incentivise scientists • Create a forum for sharing and rewarding best research proposals based on impact (e.g., a National level biannual symposium/conference, similar to Bio in the US can serve to showcase advances in applied research by academia and industry. • Establishment of centres of excellence in	• R&D efforts • National level platform to showcase research proposals and findings will help propel collaboration and partnership opportunities. • Establishment of Centres of Excellence would help attract expertise, skill set training and funding support from foreign funding agencies and multinational companies.	

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
		specific disease areas such as Oncology, Neurodegeneration, Inflammation and Auto Immune Diseases can be considered, along the lines of the various institutes of the NIH.		
Indian research institutes working on their own projects with comparatively lesser incentivization for collaborative projects with leading research institutes across the world	Minimal collaborative research with foreign research institutes, thus not offering an opportunity to work in a collaborative manner and cross-learn	• Facilitate joint collaborative programs between Indian research institutes and overseas institutes to provide real-time exposure to techniques and thinking of collaborating researchers around the world. • Permit public sector researchers to collaborate with anyone within a basic defined framework without having to seek permission from superiors • Establishing Tech-Transfer / Business Development cells in major academic institutes • Permit public institutions to	• Enhanced collaborative research, leading to more effective R&D • Such collaborations are critical for research and would encourage innovation within India • Creating Tech transfer/business development cells will facilitate identification of opportunities for collaboration or licensing of technologies or products. It will also enable a common understanding between academia and industry partners in terms of clinically translatable assets.	Medium

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
		directly gain commercial benefit from intellectual property created within the institute		
Medical education curriculum focused purely on clinical subjects, with no exposure to non-clinical laboratory sciences and research (e.g., molecular biology)	Inability of clinicians to conduct research involving clinical aspects and pure science/ basic lab research	• Medical education should have a good mix of clinical and laboratory based non-clinical sciences • The standard of non-clinical science curriculum (including GxP training) should be brought on par with international curriculum. • Clinicians in public teaching hospitals must compulsorily be required to collaborate and publish work relating to basic laboratory research	• Inculcating a scientific research-based mindset among clinicians • Overall Improvement in the quality of clinical research as well as specifically within clinician's practice	Medium
EHR Standards for India	There are different EMRs that exist in the ecosystem. Launched in 2013, EHR standards of India have not been updated since then; there is an ardent need to come out	Harmonization of EMRs	96% of hospitals have an EHR federally tested and certified for the government's incentive program in the US.	High

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
	with the next version of the same as well as regulations for hospitals to use EHRs as a mandate.			
Indian Regulatory Agency depends on clinical and scientific expertise of academic clinicians during the approval process	No opportunity for formal pre-submission scientific discussions with the agency, unlike all other regulated countries	• Build capacity within the regulatory agency by hiring scientists, researchers, clinicians who can advise on scientific matters related to submissions during pre-submission meetings. • Engage persons of Indian origin working in regulatory agencies in other well-regulated countries	• Enhanced quality of submissions for scrutiny • Drug R&D focused on the needs of the country • Save time during review process for both sponsors and regulatory agency • Regulations aligned to cutting-edge science	Medium
• Scarcity of high quality Phase I units in India • Phase I studies for molecules discovered outside India are not permitted in India.	• Indian companies have to go overseas to conduct Phase I studies • Several high-quality Phase I units in India had to be shut down due to inadequate volume of studies	• Permit Phase I studies for molecules discovered outside India for defined therapy areas that are of relevance/ priority to Indian population. • Put in place robust safety measures to ensure study participant safety.	• Phase I is the most highly scientific and challenging part of drug development. • Phase I units are not commercially viable without demand from overseas • Studies conducted for submission to	High

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
			key regulated markets will enhance quality of services and expertise of Indian clinical scientists	
Quality of GxP inspections is sub-optimal leading to findings exposed by foreign agencies	Quality of GxP inspections	• Establish a syllabus for structured training program for all GxP inspectors- classroom and onsite • Mandatory qualifying examination and requalification on a periodic basis • Engage inspectors from regulated frontline markets on 2-year assignments	• This will enable bringing India GxP inspections on par with international inspections • Will ensure India passes all international inspections • Boost global confidence in and acceptance of data from India	High
Lack of clear Structure, organogram and decision making process within the Indian regulatory agency	• Current regulatory agency structure is fragmented and processes are sub-efficient. • Many decisions rest with just few individuals, unlike in other evolved regulatory agencies where there are separate departments within regulatory	• Organization structure that optimizes the efficient flow of applications through the review process from submission to regulatory decision in time bound manner is essential. Evolved regulatory agency structure like	• Bring Indian regulatory agency on par with other developed agencies. • Greater confidence among global stakeholders in the data review and approval systems of Indian regulatory agency.	Medium

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
	agencies, leading to enhanced effective review process.	USFDA can be evaluated. • Within this structure, there is a need for strong reviewer expertise in assessing safety, quality, and efficacy, with clear remits of responsibility and justification of decisions based on science, data in a transparent manner • Regulatory agency needs to have clear written internal operating procedures to guide officials in their activities. These operating procedures, do's and don'ts, should be part of Drugs and Cosmetics Rules (as is the case with US code of federal regulations)		
Lack of epidemiological database and lack of national patient registries for various critical and life-threatening disease	Due to lack of national epidemiological databases, many decisions to consider orphan drug/indication or not are left at the	DoH or ICMR or similar such body should develop national orphan disease database, rare disease database, Severe	With introduction of orphan drug definition and accelerated and expediated pathways in new drugs and CT rules, availability of	High

Current process	Challenges / Problem	Proposal	Justification for the proposal	Impact (High, Medium, Low)
	discretion of SEC members and leading to undue ask for additional clinical data leading to delay in getting medicine in hands of patients.	debilitating or life threating disease (SDLTs) database and provide clear approval pathways, based on accelerated and expediated pathways using reliance mechanism. This will help in early access of medicines to patients.	such national epidemiological databases will help in uniform implementation of these principles.	
	discretion of SEC members and leading to undue ask for additional clinical data leading to delay in getting medicine in hands of patients.	debilitating or life threating disease (SDLTs) database and provide clear approval pathways, based on accelerated and expediated pathways using reliance mechanism. This will help in early access of medicines to patients.	such national epidemiological databases will help in uniform implementation of these principles.	
FUTURISTIC RECOMMENDATIONS				
Currently, no regulatory guidelines for • Next generation sequencing diagnosis • Software as Medical Devices • Companion Diagnostics • Tumor Agnostic Approval	• Existing clinical tests considered as research use, not adopted by institutional protocols. Patients not getting the benefit. • With digital health gaining momentum, there is a need to regulate software	Develop and establish Regulatory guidelines on clinical and germline testing using Next generation sequencing, use of software as medical devices, companion diagnostics and tumor agnostic approval.	• Similar guidelines exist for US FDA. • Bring Indian regulations on par with developed markets	Medium

FUTURISTIC RECOMMENDATIONS				
	• tools used directly/ indirectly to determine patient care. • Pathway to develop and regulate diagnostics poses several challenges. • With advent of therapies approved for pan-tumor indications, lack of Indian guidelines delineating the path for filing and approval for both testing and treatment in an expedited way			
TAX RELATED RECOMMENDATIONS				
Current incentives for R&D are being phased out or being reduced	Inadequacy of incentives supporting drug discovery	Provide tax credit for NCEs/NBEs discovered in India which can be set off against future revenues. *(1) Long-term tax holidays (same as under Section 80-IB of IT Act, expired in Mar-17)* *(2) Weighted (additional) deduction of expenses up to @100% of costs for NCEs/NBEs discovered in India (same as under Section 35(2AB) of IT Act, expired in Mar-20)*	• Improved access to capital as the investments become more attractive • Policies aligned with progressive economies that actively encourage R&D investments through supportive taxation	High

TAX RELATED RECOMMENDATIONS				
		(3) Deduction of Capital Expenditure on R&D Building (refer to Section 35(1)(iv) of IT Act)		
	Limited availability of low cost capital	• Cash grants for NCE/NBE programs originating from India *(A) 50% grants/soft loans to support clinical proof of concept studies conducted in India for NCEs/NBEs discovered in India* *(B) Innovation grants for discovery efforts in priority areas (high unmet needs)* *(c) Long term funding at concessional rates of interest backed by government to support translational development for commercializing IP generated by Indian academic institutions (including ones licensed to for profit companies)*	• Improved ability of Indian innovators to generate clinical proof of concepts and attract additional funding • Incentivizes R&D in unmet clinical needs (E.g.: Head & Neck Cancer, MDR infectious diseases, etc)	High
Tax exemption of R&D inputs	Several critical components are not covered, Lack of clarity	• Tax exempt importation of reagents,	Improves much needed liquidity	High

	in interpretation and execution	consultation and R&D services to support the development of NCEs/NBEs discovered in India (A) *Currently exemption is only for purchase of specified goods. The exemption should cover purchase of RLD, Raw Materials, API, Cell Lines, Laboratory Chemicals etc. + all types of services.* (B) 100% exemption from payment of Custom Duty and GST on import and local purchase of all goods and all services – shall release much needed liquidity which is locked in. (c) Exemption from payment of RCM on import of all services irrespective of place of provision of service (D) Speedy refund of accumulated Input Tax Credit considering the high gestation period,		

TAX RELATED RECOMMENDATIONS				
		uncertainty of outcome; and low success ratio. (E) Benefit on gross (instead of net) foreign exchange earned under Service Export from India Scheme (SEIS); and Duty Credit Scrip (DCS) earned should be freely marketable.		



ABOUT FICCI

Established in 1927, FICCI is the largest and oldest apex business organisation in India. Its history is closely interwoven with India's struggle for independence, its industrialization, and its emergence as one of the most rapidly growing global economies.

A non-government, not-for-profit organisation, FICCI is the voice of India's business and industry. From influencing policy to encouraging debate, engaging with policy makers and civil society, FICCI articulates the views and concerns of industry. It serves its members from the Indian private and public corporate sectors and multinational companies, drawing its strength from diverse regional chambers of commerce and industry across states, reaching out to over 2,50,000 companies.

FICCI provides a platform for networking and consensus building within and across sectors and is the first port of call for Indian industry, policy makers and the international business community.