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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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★ **New export strategy may focus more on key component** *(Page No. 49)*

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IDMA BULLETIN

Vol. No. 52 **Issue No. 25** **01 to 07 July 2021**

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Meeting with Dr Rubina Bose, DDC(I) and Shri A Senkathir, DDC(I) at FDA Bhawan CDSCO, Mumbai

Dr. Rubina Bose, DDC(I) has been transferred from CDSCO, West Zone, Mumbai to CDSCO (HQ), New Delhi and Shri Senkathir, DDC(I) takes her place at Mumbai.

Our National President Mr Mahesh Doshi, Hon. General Secretary, Dr George Patani and Secretary-General, Mr Daara B Patel thanked Dr Bose for all her support and active participation in IDMA activities and bid farewell to her and welcomed Shri Senkathir.

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IDMA representation on PLI 2.0 Suggestions/ Clarifications to DoP - reg.

The Association has submitted a representation on 26th June 2021 to Shri Navdeep Rinwa, IAS, Joint Secretary to the Government of India, Department of Pharmaceuticals on the above subject :

Greetings from Indian Drug Manufacturers' Association.

This has kind reference to the discussion our National President Mr. Mahesh H Doshi had with your goodself and is further to our communication of 17th June 2021 regarding PLI 2.0. We are giving below our suggestions/ clarification points for the PLI 2.0 for your consideration:

- If there are common Directors / Shareholders in two Companies, can that be considered as a Group Company?
- MSME may not remain in the MSME Criteria during the tenure of the Scheme. Will it be still eligible for Incentives as per the Scheme or it has to remain MSME for the entire tenure.
- Can DMF's be also considered as Criteria / Weightage for API Companies in Selection parameter?
- For 50% weightage – in place of Number of Plants in MSME Group having certain accreditations, Investment made in Plant & Machinery and Research and Development expenditure in last 5/10 years may be considered.
- In case accreditations criteria is retained, equivalent certifications to US-FDA such as Korean MFDS approvals (as also form other PICS Members) need also be considered on same level of weightage.
- 7.1.2 says for Group B threshold sales in 2022-23 for eligible products should be GREATER THAN Rs.10 Crores from the base year 2019 – 20. If there are no sales in 2019 – 20 then the Base year sales can be considered ZERO for threshold sales? The same will apply for Incentive calculation?
- If the investment in one year is less than the average minimum investment and in the subsequent year it is more so that the cumulative investment of both the years put together is as per Minimum Cumulative Investment Criteria, is that allowed and will be eligible for Incentive?

Yesterday, we had sent a mail to Dr. Sumit Garg, Deputy Secretary. The same is reproduced below for your kind reference:

For the purpose of defining Group Company, the guidelines have made use of definition as in FDI Policy Document of 2020. This restricts the applicants only to those Companies which strictly fall within this definition.

We wish to point out that in case of MSMEs there are many Companies which are Family owned, with shareholding distributed amongst close family members.

Shareholdings of these Companies are closely held within the family and hence, they have absolute control to "voting rights" as also "appointment of Directors on the Board" within the family who own all "Group Companies".

There is a need for inserting suitable clarification to consider all such Companies as "Group Companies" for the purpose of this Scheme. Alternatively, internal guidelines be issued to SIDBI to accept the contention of the applicants falling within this category.

Looking forward to your favorable consideration.

Thanking you

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PLI 2.0 Scheme - Clarifications by the Technical Committee and FAQs – reg.

Attention Members

The Association has received an email communication from Team PLI-Pharmaceuticals, DoP/SIDBI dated 02.07.2021 on the above subject as reproduced below:

Based on the queries received from various interested applicants/ associations, FAQs have been prepared and uploaded in the Scheme Instruction/ Circular section of the PLI-Pharma Portal by PMA on July 01, 2021. You may also like to go through the same for better understanding of various aspects of the scheme. For the convenience of the users, the FAQs have been sub-grouped into various sections viz., Applicant and Application, GMR, Eligibility, Selection Parameters etc. Further, separate clarifications have been provided for queries which were referred to the Technical Committee in respect to various products and their eligibility/ categorization.

Link to the Scheme Instruction/ Circular section is given below for ready reference.
https://pli-pharma.udyamimitra.in/Schemes/SchemeInstructions

Enclosure : 1. FAQs- PLI Scheme for Pharmaceuticals - Clarifications from Technical Committee

2. FAQs- PLI Scheme for Pharmaceuticals

Frequently Asked Questions- PLI Scheme for Pharmaceuticals Clarifications from Technical Committee (TC)

Disclaimer: The FAQs and their replies have been made for ease of understanding of the Operational Guidelines of the scheme dated 1st June 2021, read with Corrigendum dated 30th June 2021. Replies to FAQs reflect the best possible interpretation of the questions asked by the industry members. In case of any difference in any aspect of scheme that emerges post release of the FAQs, the Operational Guidelines dated 1st June 2021, read with Corrigendum dated 30th June 2021 will prevail over the FAQ.

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औषध विभाग Department of Pharmaceuticals

sidbi

1	Does Phyto Pharmaceutical Ingredients (PPI) are included in this scheme, if yes what would be the criteria for them? Do we need to have the approval to manufacture the PPI prior to apply in that scheme? Because it will be single herb ingredient, will PPI be treated as API or as finished product? For manufacture of PPI finished product, do we have to use raw herb or we can use processed extracts of the plants?	Phyto Pharmaceuticals are already covered under sub-category 8 of Category 1 of PLI scheme. Under New Drugs and Clinical Trial Rules 2019, Phyto-pharmaceutical drug is defined as a drug of purified and standardised fraction, assessed qualitatively and quantitatively with defined minimum four bio-active or phytochemical compounds of an extract of a medicinal plant or its part, for internal or external use on human beings or animals, for diagnosis, treatment, mitigation or prevention of any disease or disorder but does not include drug administered through parenteral route. If any product which attracts the aforesaid definition will cover under the category of phyto-pharmaceuticals.
2	Kindly clarify whether the following products are covered by PLI or not. • Intravenous maintenance infusion • Clinical nutrition infusion • Enteral nutrition • Antibiotics intravenous injection	All these products appear to be formulation products. Various formulations are already identified as per their therapeutic action under subcategory 2 of Category 3 of the scheme such as Autoimmune drugs, anti-cancer drugs, anti-diabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs and anti-retroviral drugs. Unless the composition and therapeutic use of the product is not known, the committee is unable to offer any comments. All these products appear to be formulation products. Various formulations are already identified as per their therapeutic action under subcategory 2 of Category 3 of the scheme such as Autoimmune drugs, anti-cancer drugs, anti-diabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs and anti-retroviral drugs. Unless the composition and therapeutic use of the product is not known, the committee is unable to offer any comments.
3	In relation to anti-infective drugs under Category 3, whether premix drug product (without holding patent itself) is within the scope of PLI or not.	Composition and therapeutic action of premix is required before making any comments on the same.
4	Whether the following scenario can be considered as single product or individual (separate) product for PLI scheme application? •Different strengths of same formulation containing same API (e.g., Paracetamol 250 mg 500 mg 650 mg). •Immediate release (IR)/modified/sustained release (SR) of same formulation (Vildagliptin 100 mg IR tablets and Vildagliptin 100 mg SR tablets). •Different dosage forms of same formulations (Tablets/Injections etc.) •Insulin formulations such as Insulin Regular, Isophane Insulin, Biphasic Isophane Insulin 30/70, Biphasic Insulin 50/50.	As the scheme covers broad categories of products under three (03) major categories like Biopharmaceuticals, Complex generic drugs, Orphan drugs, Complex excipients, APIs, Autoimmune drugs, anti-cancer drugs etc., the products covers under these categories irrespective of their strength and dosage form are covered.

5	Are Home healthcare medical devices like Digital Blood Pressure Monitors, Nebulizers, Pulse Oximeters, Thermometers, Body composition monitors etc. being considered for PLI scheme? If no, then why not? Any specific reason? How can you help facilitate addition of these devices under PLI scheme? (These devices are needed in every household.)
	All of these are Medical Devices which are not covered in the present scheme.
6	Can examples be provided of Drugs which are included in Bio-pharmaceuticals, Orphan Drugs, Complex Excipients, Phyto-pharmaceuticals?
	Biopharmaceuticals: Vaccines, r-DNA products etc. Orphan Drugs: "Zolgensma" for treatment of spinal muscular atrophy. Complex Excipients: Copovidone, Carbomer971P etc. Phytopharmaceuticals: AQCH (by M/s Sun Pharma, under clinical trial in the country)
7	Do medical devices include invitro Diagnostics Reagents kits in this scheme?
	Only IVDs are included in the scheme.
8	It is mentioned that Special capsules like HPMC, Pullulan, enteric etc. We need clarification "etc." means which extra product is included.
	Clarification will be provided on case-to-case basis.
9	Since vaccines are Bio-pharmaceuticals, we would like to have confirmation that we would be eligible under product category 1 listed in Appendix 1 of Operational guidelines for the Production Linked Incentive (PLI) Scheme for Pharmaceuticals.
	Vaccines comes under sub-category 1 (Biopharmaceuticals) of category 1 of the scheme.
10	Will products such as Losartan tablets, Atorvastatin Tablets, Sertraline Tablets, Metformin Tablets, Glimepiride Tablets (formulations), Fluoxetin Capsules etc. be allowed under the scheme? (If required, we can forward our full list of products for verification.)
	All these formulation products are already covered under sub-category 2 of Category 3.
11	Which APIs would be given priority?
	APIs under category 2 are eligible (except for those which are covered in earlier PLI scheme) under the scheme. However, there is no such provision is specified in operational guidelines to accord any priority for API.
12	During the change of the product after the first year, can we include Para amino phenol in choice of product?
	Para aminophenol is already covered under earlier PLI scheme, hence will not be covered under the current Scheme. Please refer to Appendix A of the Operational Guidelines.
13	Our company specializes in manufacturing stabilized grades of Vitamins used in various applications by Indian manufacturers. We are group of professionals who have worked extensively in the pharmaceutical industry in India and are currently involved in providing products which are good import substitutes to imports from various countries. We would like to know under which category of the PLI scheme we will be able to apply for availing this scheme.
	Vitamins covered under category 2 (except for those which are covered under earlier PLI scheme) of the scheme.
14	What are the products under IVD devices category of the Scheme?
	Only those instruments and systems, which are exclusively and directly involved in the collection, preparation and examination (including processing and detection of results) of specimens taken from the human body such as PCR Plate, ELISA Reader etc. may be considered as other IVDs for inclusion in the present scheme.

Frequently Asked Questions- PLI Scheme for Pharmaceuticals

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Disclaimer: The FAQs and their replies have been made for ease of understanding of the Operational Guidelines of the scheme dated 1st June 2021, read with Corrigendum dated 30th June 2021. Replies to FAQs reflect the best possible interpretation of the questions asked by the industry members. In case of any difference in any aspect of scheme that emerges post release of the FAQs, the Operational Guidelines dated 1st June 2021, read with Corrigendum dated 30th June 2021 will prevail over the FAQ.

A. Applicant and Application (including Standard Formats) related FAQs

1. We understand from Appendix K that a single application has to be made by a company for multiple products falling in different categories. Kindly confirm.

Yes. Single application is to be made, whether it is for one or multiple products.

2. Clause 9.4 mentions that selected applicants shall submit sales data for the base year FY 19-20, domestic value addition plan etc. as required by PMA / DoP. It would help to provide the format for the same– also why is domestic value addition plan required as the same in not a criterion at all in the Scheme.

It is clarified that domestic value addition is not a criterion in the scheme, however, information regarding the same may be collected.

All requisite formats will be shortly available on the scheme portal.

3. Is there a requirement to submit a projection/project report with respect to future investments as part of the application process?

A brief technical plan on investments, proposed locations, project cost, means of finance, implementation plan etc. would be required to be submitted by all selected applicants.

4. Whether an applicant, who is MSME at the time of making an application, commit investment in P&M, more than INR 50 Crores and still be considered as MSME for the whole tenure of the said scheme? Will the applicant continue to receive incentives as MSME applicant even after surpassing the MSME limits as per MSMED Act?

Yes. As per clause 2.2.3. grouping of the applicant under MSME category is subject to applicant's registration as Micro, Small & Medium Enterprises (MSME) with the Ministry of MSME, Government of India. Upon selection under the scheme, the MSME applicant will be eligible for incentive based on the yearly threshold criteria of minimum cumulative investment (Committed Investment in case of MSME) and minimum percentage growth in sales of eligible products as mentioned in Appendix B of the guidelines. As such, the scheme does not provide any restriction for MSME applying under the Scheme and can graduate to non-MSME entity based on its investments under the Scheme and other investments during the tenure of the scheme.

5. We are a newly formed company in FY 2020-2021 in the Category 2 API/ Intermediates. Most likely our commercial production is going to kick off in the current financial year 2021-2022. Since this PLI Scheme have the base year as FY 2019-2020 for computing GMR and incremental sales we will not have be having the same. We do not have any parent company with a similar business. Ours is a newly formed company. We will fall under Group C – MSME.

Are we eligible on the basis of proposed investment to apply in PLI Scheme? We will be incurring on Machinery, Equipment, product registration, R&D, Building, associated infrastructure etc. How the incentive in our case will be computed?

GMR is nil in your case, however, the Operational Guidelines does not specify a lower limit for GMR. Hence you will be eligible to apply for the Scheme under Group C. However, several selection criteria involve historical data of the applicant/ group companies, on which final ranking and selection would be done.

In case you are selected, all base year data will be taken as Nil, and incentive calculations will be made on the basis of that, subject to meeting other criteria of investment and sales achievement in the years between FY 2021-22 to FY 2027-28.

B. Global Manufacturing Revenue (GMR) and Group Company related FAQs

1. If there are two entities in the same group company (parent-subsidiary) where parent qualifies under Group A and subsidiary qualifies under Group B basis its products and standalone revenues and basis the total GMI and R&D expenditure of the parent & subsidiary taken together, subsidiary may qualify under Group A.

In such a scenario, can the subsidiary make an application under Group B and comply with the minimum cumulative investment and threshold net incremental sales for required for Group B?

Grouping of the applicants under the scheme (A/ B/ C) would be based on the GMR as defined in clause 2.12 of the operational guidelines and the applicant would continue to remain in the same group (A/ B/ C) during the entire tenure of the scheme.

Once the group of any applicant is decided as above, the applicant will have to comply with necessary parameters (selection parameters as defined in Clause 4 and incentive criteria as defined in appendix B) pertaining to that group.

2. Whether sales of goods procured/ manufactured on a loan license/ contract manufacturing basis would be eligible for incentive under the Scheme. Whether trading revenue (P2P) & contract mfg. LLM (Loan License Manufacturing) to be included as part of global manufacturing revenue? P2P Revenue should be excluded while LLM revenue can be included.

In case the sales of products manufactured under contract manufacturing/ LLM is booked as manufacturing revenue in the books of accounts and Statutory Auditor's certificate is submitted by the applicant as per the Scheme, the same would be considered for calculating GMR. Trading revenue shall not be considered for GMR.

3. In calculation of GMR for base year – Is export incentive included?

No, as only manufacturing revenue of the Applicant/ Group Companies is being considered in the definition of GMR given in clause 2.12 of the Operational Guidelines.

4. For calculating GMR - I goods are procured on a contract manufacturing basis, would the revenue from sales of such products would be counted towards GMR.

In case the sales of products manufactured under contract manufacturing is booked as manufacturing revenue in the books of accounts and Statutory Auditor's certificate is submitted by the applicant as per the Scheme, the same would be considered for calculating GMR.

5. GMR - Consider a scenario, where the product manufacturing is completed at Factory A in the USA and such product is invoiced to Sales office in Singapore at ex-factory price and finally sold to a third-party customer from Singapore at sale price. For calculating GMR whether ex-factory price to be considered or the sale price to the end customer please clarify?

Ex-factory prices, as certified by Statutory Auditor Certificate, will be considered in the instant case.

6. This is regarding a query on the "Group Company" definition as per Pharma PLI Guidelines:

The Applicant is a subsidiary of a Pharma Company incorporated in Singapore. There is a chain of about 20 companies in between the Ultimate Holding Company in USA and the Applicant.

The query is whether all the entity's turnover will be required to be considered for the purpose of Global Manufacturing revenue (GMR). (i.e) Whether GMR includes revenue of Forward Chain (subsidiary companies) and Backward Chain (Holding Companies).

Please note, that it may not be practically possible trace back the entire chain of entities.

As per clause 2.3 of the operational guidelines, Group companies shall mean two or more enterprises which, directly or indirectly, are in a position to: Exercise twenty-six percent or more of voting rights in other enterprise; or appoint more than fifty percent of members of board of directors in the other enterprise.

For the purpose of calculation of GMR, only those group companies as defined above, who have booked revenue from the manufacturing of pharmaceutical goods and/or in vitro diagnostic medical devices in their books, shall be allowed. The same shall be certified by a Statutory Auditor.

7. Clause 2.13 - Definition of the term 'group company' would cover a group company outside India as well. Confirmation needed.

Yes, provided they satisfy the conditions for Group Company laid down in clause 2.13 of the Operational Guidelines.

8. Group Company (ies) as defined in the FDI Policy Circular of 2020 shall mean two or more enterprises which, directly or indirectly, are in a position to: exercise 26% or more of voting rights in other enterprise; or appoint more than 50% of members of board of directors in other enterprise. There are PEs (e.g., Quadria, Chryscap) with stake more than 26% in multiple pharma companies.

Will such pharma manufacturing company where any particular PE has invested be covered under the definition of Group Company for the purpose of GMR and counted accordingly?

Is there any restriction that the Group Company should be based in India only – in other words, if there is a Group Company located outside India whether the same will be covered for the purpose of the Scheme A- Refer Clause 2.13 of the operational guidelines.

As per clause 2.3 of the operational guidelines, Group companies shall mean two or more enterprises which, directly or indirectly, are in a position to: Exercise twenty-six percent or more of voting rights in other enterprise; or appoint more than fifty percent of members of board of directors in the other enterprise.

Accordingly, pharma company and PE which holds 26% or more stake in the subject pharma company are group companies. However, as per the query multiple pharma companies where the PE holds 26% or more stake individually are not treated as group companies among themselves.

Group Companies may be based both in or outside India.

9. Assume that a particular applicant chooses not to include turnover of a group company and prefers to remain in a different Group (say for example Group C as compared to Group B), would this be permitted under the Scheme - Refer Clause 2.2 of the operational guidelines

This is not permitted as per the Operational guidelines. Further, you may please note that the GMR of the Applicant and its Group Companies, is an eligibility/ selection parameter. The application would require a Statutory auditor certificate in respect of the GMR of the applicant and all its group companies.

10. If there are 2 companies, whose turnover and investment are combined for the purpose of GMR and GMI (classification under relevant Group A/B/C), and basis the consolidated numbers, happen to qualify as Group A, can they both take this consolidation as a base to file separate applications for different eligible products, as Group A applicants under the scheme? Essentially, the turnover considered for group classification would be overlapping in this case.

No. Any group company will be considered as only one applicant.

C. Eligibility for Application related FAQs

1. Contract Development and Manufacturing Organizations (CDMOs) – Applicant manufactures certain products as CDMO, can such products be included in the application for PLI. Are such products eligible for incentives?

In case the Applicant is the CDMO and manufacturing eligible products under the arrangement, and the sales is booked in the P&L account of the Applicant, as certified by Statutory Auditor, then the sales shall be considered for the purpose of incentives.

2. In case of Green Field project for exports, gestation period would be 2 to 4 years. The scheme currently does not address this. For green field project, companies will not have any base year data. How, will this be addressed for computing incentive?

In respect of an applicant where the sales of eligible products for FY 2019-20 is nil, for the purpose of calculating incentive, the base year sales would be taken as zero. However, the applicant is required to achieve the threshold/ incremental sales for the subsequent years, as given in Appendix- B of the Operational Guidelines.

3. How is the PLI scheme is going to accommodate the green field investments in new company formed under section 115BAB. Can the new company (subsidiary) formed for green field projects u/s 115BAB be a co-applicant with the parent and claim the investment and production for PLI along with parent?

Co-applicants are not allowed under this PLI Scheme. Eligibility under the Scheme shall not affect eligibility under any other scheme and vice versa.

Base line data for FY 2019-20 of green field applicant will be taken as Nil and calculations of incentives will be based on that.

4. Is it mandatory to manufacture and market the products only in India or can a selected applicant export the eligible goods as well?

The approved eligible products have to be manufactured in India only. The scheme does not mention any specific market.

D. Eligible Products related FAQs

1. Since product categories are very broad, would products like generics (and not complex generics) be regarded as covered under the categories or a specific approval from DoP would need to be taken?

   As per appendix A, many generic drugs are covered under Category 3 of the scheme. In case of any doubt as to whether any particular drug is covered under this scheme or not, the same may be referred to PMA beforehand.

2. If a product is not falling under any of the given categories and approval from Technical Committee has to be taken, would such approval be granted prior to filing the application or post-filing?

   If the product is not falling under any of the given categories as per Appendix- A of the Operational Guidelines, the same shall not be considered.

3. Some Products may fall under different categories, how do we classify them in the application form?

   Categorization of the products should be done by the applicant as per the Operational Guidelines. If a product is an API/ KSM/ Drug Intermediate, then it will fall under Category 2 only. If a product is a drug formulation, then it can fall under Category1 or Category 3. In case a product falls under both Category-1 and 3, it will be considered under Category-1.

   Appendix-A of the guidelines may also be referred wherein Category-3 clearly mentions- Drugs not covered under Category 1 and 2.

4. Can eligible products falling under the 3 categories be considered together for being part of the 'product mix' under the Scheme? Further, can such eligible products be manufactured in different locations/ facilities of the applicant, including loan licensee premises?

   Yes. Applicant may apply for more than one Eligible Product, belonging to any of the 3 categories, under the scheme. Further, the eligible product may be manufactured in different locations/ facilities of the applicant in India, including loan licensee premises.

5. Whether Eligible products should be seen at sub-category level OR per molecule level OR at category/overall level

   Categorization of the eligible products will be seen as per Appendix A of the Operational Guidelines.

6. Incentive to be calculated based on incremental sales of eligible products approved for the applicant. Change in product mix permitted max. five times during scheme period (until mar 28)

   How to take care of new product launches under existing sub-category or incorrect classification of sub-category [e.g. complex generic product]?

   All products with expected incremental sales under given sub-category to be included in the application list. Since scheme is for six yrs; such list should be revised typically yearly once at the time of budget.

   Yes. As the pharmaceuticals products involves complex chemicals and molecules, the scheme has a provision for a Technical Committee (TC) as per clause 2.21. In case, a clarification is needed on eligibility/ categorization of specific products, a list may be sent to the PMA, so that the same can be referred to the TC.

7. Definition for some of the sub-categories like Complex generics, orphan drugs, complex excipients etc. is not existing. What if in absence of the definition, product is categorized under Category 1 - Complex generic (10% incentive) and government rejects the same – No provision to reclassify under Category 3 – say anti diabetic?

   The product should be categorized under the correct category as per Guidelines. In case there is confusion on categorization of a specific product, the same may be referred to the PMA beforehand.

8. What about product mix changes - Policy gives limited number of changes to be allowed. Market dynamics may force to reconsider product mix in the investment site.

The policy has considered the same and has allowed change of products to the extent of five times vide clause 7.2.2 of the Operational Guidelines.

9. Appendix A provides category 1, category 2 and category 3 of eligible products. However, scheme does not define what would be covered under each of the line items mentioned therein (eg what is covered under complex generic drugs and what would not be considered as complex generic drugs).

Whether the word "Drug" as referred in the Category 1 and 3 of goods includes API or covers only formulations?

Guidelines would be required to have consistency of what gets covered under Category 1 products and not under Category 3 and vice versa. What is the key differentiator / criteria of Category 1 and Category 3 products eg other drugs as approved are covered in both the said categories? This is relevant as the incentive rates changes significantly under both categories.

As the pharmaceuticals products involves complex chemicals and molecules, the scheme has a provision for a Technical Committee (TC) as per clause 2.21. In case, you need clarification on eligibility/ categorization of specific products, you may send us a list, so that the same can be referred to the TC.

Only Category 2 is for APIs, Category 1 and 3 covers the drug product/ formulations. In case a product falls under both Category-1 and 3, it will be considered under Category-1. Appendix-A of the guidelines may also be referred wherein Category-3 clearly mentions- Drugs not covered under Category 1 and 2).

Decision for the Other drugs sub-category in both Category 1 and 3 would be taken by DoP, as explained in Appendix A of the Operational guidelines.

10. New products manufactured in the 2nd or 3rd year of the tenure of the scheme: In case company applies for the Scheme for products which it starts manufacturing from FY 2023-24/2024-25, there will be no revenue for those products in FY 2022-23. Can such products be eligible under the Scheme?

Yes, it can be eligible.

However, year in which (say FY 2022-23) the sale of the said eligible product is nil, incremental sale of that product will be considered as zero and no incentives will be given for that particular year.

E. Selection Parameters and Ranking related FAQs

1. Whether ANDAs approved or ANDAs applied for to be considered? Whether other regulated markets (e.g. EMEA, BfArM, ANVISA), should be included?

NDAs/ANDAs approved are to be considered only.

As the intention is to consider only highly regulated markets, and EMA has already been included, approval by Regulatory Bodies mentioned in the Operational guidelines only will be considered.

2. Would capital investment in R&D get included under the two qualifying criteria viz. GMI (with 30% weightage) and R&D expenditure (with 40% weightage)?

In selection criteria-1 (for Group A/B applicants) the Gross manufacturing investment in India, includes capital investments for R&D facilities.

In selection criteria-3 (for Group A/B applicants) R&D expenditure (in India or abroad) will include both capital and revenue expenditure.

3. Clause 4.1 – One of the selection criteria is Gross manufacturing investment for the past 10 years. Whether such gross manufacturing investment would be considered on an average basis or would be seen in totality? Case in Point: Companies/ groups which are relatively new, i.e., which have been set up in FY 2017 or thereafter, would have made comparatively lesser investment.

The selection of Applicants will be based on Gross Manufacturing Investment (GMI) of Applicant/ Group Company in India for 10 years as given in Para No. 4 of the Operational Guidelines.

Accordingly, the GMI will be the total value.

4. Would such applicants rank lower vis-a-vis an applicant which has presence for the past 10 years, and therefore greater total investment amounts.

All eligible applicants shall be ranked on the basis of marks obtained in the evaluation criteria given in Appendix J of the Operational Guidelines. The applicant securing highest marks shall be ranked 1 followed by Applicant securing second highest marks. The selection of the Applicants shall be in order of their ranks vide clause 4 of the Operational Guidelines.

5. Whether other regulatory approvals like WHO PQ, consistent track record of supplying quality pharmaceutical products without any disqualification, Process Patents knowledge etc. are amongst other factors that would be considered by DoP while evaluating the applications?

Eligibility criteria and Selection criteria is clearly defined in clause 2.1, 2.2 and clause 4 of the Operational Guidelines, respectively. No other criteria would be considered for selection.

6. For the purpose of determining past manufacturing investment and R&D expenditure, would expense booked in financial statements be regarded as eligible?

Would such expense incurred outside India by applicant/ group company be considered?

As per clause 2.22 of the Operational Guidelines, gross capital investment in pharmaceutical and in vitro diagnostic medical device manufacturing facilities including capital investments for R&D facilities will be considered for arriving at Gross manufacturing Investment.

Accordingly, such investments as defined above which are capitalized in the books of accounts and certified by the Statutory Auditor will be considered for the purpose.

Investment made outside India shall not be a part of GMI as used in selection criteria-1 for Group A/B/C (Non-MSME) Applicant.

However, R&D expenditure made outside India shall be considered while computing R&D expenditure used as selection criteria-3 for Group A and B applicant.

7.	Gross Manufacturing Investment (GMI) is an important criterion for selection – The same has been defined in clause 2.22. This will include gross capital investment in manufacturing facilities including capital investments for R&D facilities. Guidelines should be provided to ensure that there is consistency in disclosure of the same for application purposes– for e.g. say in FY 19-20 there could be CWIP (whether the same should be included in GMI), also say an applicant has in the period from 10-11 to 19-20 acquired an entity for a consideration which includes certain intangibles such as IP, product patents, goodwill etc. Will the same be considered as "Gross manufacturing investment" for selection? What should be factored in GMI in case of acquisition of other entity?	As the term suggests, GMI would include capital investments in Manufacturing facilities. Typically, CWIP in the FY 2019-20 may not be considered under GMI, as the same does not guarantee conversion to manufacturing assets until the completion of the project. Intangibles shall not be allowed. In case of acquisition by the Applicant, the net asset value of acquired manufacturing facilities in the books of the applicant based on the acquisition cost for the manufacturing facilities (as in clause 2.22) at the time of acquisition as certified by the statutory auditor/ ICA shall be included for the purpose of calculation of GMI.
8.	Clause 4.1 as part of selection criterion refers to number of ANDA/ NDA of applicant/ group company from either UDFDA/ EDQM/ UK MHRA/ PMDA/ Health Canada/ TGA as on 1 April 2021. The same does not refer to US DMFs/ European CEPs which is the ANDA counterpart of APIs. Given that many API Companies fall in category B, this puts API companies at a disadvantage. Need clarification for the same Do ANDA/ NDA be necessarily owned by the Indian company applicant? Since the guidelines consider the ANDA/ NDA of the applicant as well as group company, any ANDA/ NDA even in the name of parent company or any other group company (overseas as well) may be considered for the selection criteria process. – Need confirmation on this interpretation	Corrigendum/Addendum dated 30.06.2021 has been issued by DoP regarding the same. The same is available on the website of the DoP/ SIDBI. As per clause 4.1, weightage will be assigned for Number of ANDA/ NDA of applicant/ group company (both domestic and Foreign).
9.	In respect of the 3 parameters of selection criteria – criteria 1 depends on GMI which would include the capex incurred for R&D. Criteria 3 refers to R&D expenditure which would include Capex incurred on R&D. Accordingly, is it the intent to allow factoring the quantum of R&D expenses in both criteria 1 and 3 (for years 17-18 to 19-20) from eligibility weightage perspective? Would request clarification on the same- Reference to Clause 4.1 on selection of applicants	In Selection criteria-3 (for Group A/B applicants) R&D expenditure (in India or abroad) will include both capital and revenue expenditure. Only expenditure incurred during the year would be allowed for R&D expenditure. Non-cash expenses, such as depreciation, etc., will not be allowed.
10.	Selection Parameter Sr. No.1: 3 R&D expenditure is this includes only R&D expenses (Accounted in P&L) or also R&D spend in capital in nature?	Both capital and revenue expenditure under R&D shall be considered.

F. Selection Procedure related FAQs

1. Clause 4.6 refers to Foreign MNCs, which is not defined - would help to clarify the same as the same would be relevant from selection standpoint. Also, Appendix I which is checklist for preliminary assessment of application by PMA does not have any reference to category of Foreign MNC

   An Applicant registered in India and having more than 50% shareholding by foreign company(ies) (as defined in Companies Act, 2013) may be considered as a foreign MNC for the purpose of consideration under the Scheme.

2. Clarity on timelines for DoP approval of applicants shortlisted by PMA.

   As per clause 9.2, timeline for selection is 90 days from the date of closure of application window.

G. Eligible Investment related FAQs

1. What if part assets are purchased initially and then later after two years these were sold by the company (reason could be new technology, new equipment with better capacity is available)

   Gross Investment value of the said sold assets would be deducted from the Cumulative Investment for that year in which sale is made.

2. If there are assets created at CMO plant, will they be considered under the scheme as investment?

   The assets created by Applicant should be capitalized in the books of accounts of the applicant as certified by the Statutory Auditor or Independent Chartered Accountant, whichever is applicable, except the eligible investments with respect to expenditure on R&D, product registration which may be in the nature of capital/ revenue expenditure where such is certified by the Statutory Auditor/ ICA. It may be noted that sales of products got through Contract Manufacturing will not be permitted for calculation of incentives as per the Operational Guidelines.

3. Whether investment to be seen based on cash outflow or based on capex invoice dt or based on actual capitalization? [Investment should be seen as per invoice dt of capex incurred.]

   Both invoice date and capitalization should be within the investment period (FY 2021- FY 2026) under the scheme. For any particular year, the investment will be considered under eligible investment based on the capitalization of the asset in the books of accounts for that year.

4. If a product is likely to commercialize in FY 27-28, but R&D and capex are incurred before, can the investment still be considered?

   In case the eligible product, which is likely to commercialize in FY 2027-28, is committed during the time of Application, eligible investment made towards P&M or R&D (as defined in clause 2.15 of the Operational Guidelines) in respect of the committed product, from 01.04.2020, can be considered under the scheme.

   If the same product is committed by the Applicant at the time of later change (as permitted by clause 7.2.2 of the Operational Guidelines), eligible investment made towards P&M or R&D (as defined in clause 2.15 of the Operational Guidelines) in respect of the committed product, from the date of approval by DoP, can be considered under the scheme.

5. If the expense incurred on exhibit batches would be regarded as eligible expenditure?

   In case expenditure of exhibit batches are towards R&D purpose, incurred in India during the period 01.04.2020 to 31.03.2026 and the same is booked under the R&D head in the books of accounts and certified by the statutory auditor, the same shall be considered under eligible investment.

6. Will purchase of samples be considered in R&D expenses.

   In case purchase of samples are towards R&D purpose, incurred in India during the period 01.04.2020 to 31.03.2026 and the same is booked under the R&D head in the books of accounts and certified by the statutory auditor, the same shall be considered under eligible investment.

7. A company which has applied under the earlier PLI Scheme for API/KSM in 2020 but was not selected for whatever reasons. However, one of such APIs does flow into the formulation and gets covered under the eligible Product list under the new PLI Scheme of June 2021.

   In this case, whether the investment made in the API site to create such API capacity can be considered for calculating the Rs. 200 Crs per year investment from the Base Year (after 1-04-2020) as defined in this PLI Scheme of June 2021?

Yes, if the API produced from the investment is being used only in the manufacturing of the drug formulation (which is an eligible product under current PLI Scheme) by the applicant. The investment made in such site on or after 01-04-2020 may be considered as eligible investment subject to the same being certified by the statutory auditor of the Applicant.

8. Para 2.15.3 of the guidelines provides for expenditure incurred on Transfer of Technology agreement.

In connection to the same, whether expenditure incurred on 'in-licensing milestones payments' will be considered as part of Transfer of Technology agreement or not being "Eligible Investment".

To be considered under the eligible investment, the "in-licensing milestones payments" expenditures should be made towards the cost of technology and initial technology purchase in relation to the eligible product. The same should be clearly defined in the formal legal document in respect of the licensing agreement between the parties. The expenditure is also to be capitalized in the books of accounts of the applicant.

9. Whether investment needs to be made in own factory or can be made even in Job worker location since intermediates would be manufactured by job worker on behalf of principal manufacturer and in-turn would be used by the principal manufacturer

Investments made on the eligible plant & machinery [including expenditure on associated infrastructure] subject to capitalization of the expenditure in the books of accounts of the applicant and compliance to the conditions laid down in clause. 2.15 and clause 6 of the operational guidelines.

10. We understand that investment criteria include investments made on or after April 1, 2020 & linked to product category. We need clarity on:

a. Whether incentives are linked to product from new investment only or includes incremental sales even from prior investments.

b. Whether investment will be at a group company level or individual entity level.

a. The incentives are linked to incremental sales even from prior investments subject to compliance to the conditions pertaining to investment as per clause 2.1.5 & Appendix-B (year-wise minimum cumulative investment by per Participant is given).

b. As per the definition given in clause 2.1, an Applicant for the purpose of the Scheme shall be any Proprietary Firm or Partnership Firm or Limited Liability Partnership (LLP) or a Company registered in India. Accordingly, investment will be at an individual entity level.

11. In case of application for multiple products, whether the investment and sales criteria to be met for each product or for all products put together?

Applicant presently has multiple manufacturing facilities across India and the products to be included in PLI application will be manufactured in all such manufacturing facilities. Applicant makes capital investments for improvements or enhancement of production capacities of all the manufacturing plants which includes facilities for manufacturing products under application. Can such investments made at entity level be considered as eligible investments under the PLI scheme?

Investment and sales criteria are to be met on an aggregate basis for all approved eligible products.

Investment made in the manufacturing plants that belong to the same applicant and not the group company(ies) and also conform to the Eligible Investment criteria as laid out in clause 2.15 of the Operational Guidelines will be eligible. Please also be guided by clause 6.2.3 of the operational guidelines.

12. Should the eligible investment be restricted to a green field project?

There is no specific requirement that the investment to be made for eligible products should be only in a green field facility. The same could be for expansion of current facilities as well. Further, it was specifically clarified that the Plant, Machinery and Equipment of the Project approved under the Scheme can be used for manufacturing of other pharmaceutical goods as well, subject to a declaration by the applicant.

The interpretation is correct. For threshold/ incremental sales, both sales of eligible products from existing or new facility may be considered.

13. Should there be a clear nexus between the investment and the incremental sale of eligible products?

While the guidelines state eligible investment means expenses incurred in relation to the eligible products, there is no specific requirement of nexus between the investments with the eligible products. For example, as regard the expenditure incurred on Transfer of Technology (ToT) agreements, the same is defined to include only the expenditure on cost of technology and initial technology purchase in relation to the eligible product.

However, for new Plant, Machinery, Equipment and Associated Utilities, no such requirement is specifically provided in the guidelines. Further, it was specifically provided that the Plant, Machinery and Equipment of the Project approved under the Scheme can be used for manufacturing of other pharmaceutical goods.

Having said that, the guidelines state that the Plant, Machinery, Equipment and Associated Utilities shall be used in regular course for manufacturing of goods under the eligible product categories. Accordingly, although there is no requirement of direct nexus between the investment and the manufacture of eligible products, a declaration has to be filed each year about the usage of the machinery.

The relation between Investment and Incremental Sale of the Eligible Product would be in terms of the Operational Guidelines.

14. Whether Investment of Rs. 1000 crore on a cumulative basis (minimum 200 crore per year) over a 5-year period up to FY 2025-26 is required to be made only by the applicant company on a standalone basis or such investment can be made by more than one Indian group companies (e.g., Indian parent and its wholly owned Indian subsidiary) will be considered as an eligible investment?

Only the applicants' investment on standalone basis would be considered as eligible investment, and not of its group companies.

15. Clause 2.15 - If any capital investment is funded by an International Agency, will it qualify as eligible investment?

Yes, there is no restriction for funding by an International Agency. However, grant from Govt. of India or any State/UT Government will have to be shown separately and will not be considered towards eligible investment under the scheme.

16. Will leased assets be considered as part of investment or not?

Investment should be capitalised in the Applicants book of accounts and subject to satisfaction of all clauses of clause 2.15 and clause 6 of the Operational Guidelines.

17. Dossier fees, consultants' fees? will this also be considered in the expenses? What about current WIP projects?

No. Expenditure mentioned under clause 2.15 would only be considered.

WIP will not be considered for Investment. Only the investment (except R&D and Product Registration expenditure as per clause 6.1.5) which are capitalized in the books during the investment period would be considered.

18. Are IT assets covered under investments? In a manufacturing plant there is substantial investment in IT and is a significant part of QA/ QC/ Manufacturing– it is suggested that this should be included. In current regulated environment industry invests a great deal in IT.

Expenditure on IT systems as a part of QA/ QC/ Manufacturing is incorporated in the operational guidelines vide Corrigendum/ Addendum dated 30.06.2021. The same is available on the website of the DoP/ PMA.

19. Whether investment will be considered on proportionate basis in case the investment in plant and machinery is done for both eligible as well as non-eligible products

As per the Operational Guidelines, eligible investment in relation to the eligible products only will be considered. The Plant, Machinery and Equipment of the Project approved under the Scheme shall be used in regular course for manufacturing of goods under the eligible product categories. However, this does not preclude the usage of such machinery for manufacturing of other pharmaceutical goods. The applicant must submit a declaration about usage of machinery for each year during the period that such applicant is claiming incentive under the Scheme.

20. In a certain project if there are some grants received for funding small part of the project, will the rest of the expenditure (net of grant) still be considered as investment under this scheme or total value.

Yes, the rest of eligible investment as per the Operational Guidelines, net of any Government grant received, will be considered under the Scheme, provided it satisfies all criteria mentioned in clause 2.15 and 6 of the Operational Guidelines.

21. Investments made from 01.04.2020 in respect of eligible products would be considered under the Scheme. Thus, if an investment of Rs 300 Cr has been made from 01.04.2020 till date, would the same would be considered for the minimum committed investment for FY 21-22?

Yes, eligible investment done from 01.04.2020 to 31.03.2022 will be considered under Minimum Cumulative Investment for the FY 2021-22.

22. Investment threshold is Rs. 200 Crores per year. However, in case any company, makes investment of Rs.250 Crores in Year 1 and an investment of Rs.150 Crores in the Year 2; whether the surplus investment of Rs. 50 Crores in Year 1 would be considered for calculating the total investment of Year 2?

Eligible investment as per Para No. 2.15 of the Operational Guidelines can be done as per business requirement of the Applicant, either in one go or in tranches during the Scheme Investment period. However, year wise minimum cumulative investment criteria and incremental net sales criteria both have to be met by the Applicant as per Appendix B of the Operational guidelines.

23. Whether Capital Work in Progress (CWIP) would be covered? [CWIP should be included [consistent with future investment criteria]

No. Investment should be capitalized in the books of account of the applicant during the investment period.

24. Whether land to be included? Whether Investment in intangibles (ie brand acquisition cost) to be included in investment? [As there is no specific exclusion, land/ Intangibles can be included.]

Investment on land is not covered vide clause 2.15.5 of the Operational Guidelines.

Intangibles like brand acquisition cost are also not covered as an eligible Investment head as per clause 2.15 of the operational guidelines.

25. Are R&D equipment excluded from the purview of 'eligible investment'?

It is eligible, provided it is not second-hand.

26. Whether R&D expenditure incurred outside India be considered as eligible investment?

No, R&D expenditure incurred in India only will be considered as Eligible Investment for the purpose of incentive eligibility.

May also refer to clause 2.15.4 for eligible expenditure outside India.

27. Whether expenditure on salary of staff employed in the R&D unit would be considered as eligible investment?

R&D Expenditure as mentioned in clause 4.1 and 6.1.5 of the Operational Guidelines, may include manpower cost related to R&D in India provided the same has been included under the head R&D Expenditure and certified by the Statutory Auditor as per the specified format.

28. Will litigation expenses (challenging the patent) eligible for Investment?

No, litigation expenses are not covered under the eligible investment for the Scheme.

29. We request for clarity on all the components of R&D, etc. which will be allowed and not allowed to be considered for investment as one company may leave out some components due to lack of clarity in the guidelines which other companies are considering in their application and hence lose their competitive advantage.

R&D expenditure, which has been incurred in India during the period 01.04.2020 to 31.03.2026 and the same is booked under the R&D head in the books of accounts and certified by the statutory auditor, shall be considered under eligible investment.

May also refer to clause 2.15.4 for eligible expenditure outside India.

30. If an investment of 100 Cr has been made in a new plant and only 3 out 5 products manufactured in the plant are considered for the PLI Scheme, can the full 100 Cr of investment be considered for the minimum capital contribution?

As per clause 6.2.3. of the Operational Guidelines, the Plant, Machinery and Equipment in relation to the eligible products approved under the scheme shall be used in regular course for manufacturing of goods under the eligible product categories. This does not preclude the usage of such machinery for manufacturing of other pharmaceutical goods. The applicant must submit a declaration about usage of machinery for each year during the period that such applicant is claiming incentive under the Scheme.

31. Whether a company which has applied under the earlier PLI Scheme for API/KSM in 2020 but not selected then, can now apply under this 2021 PLI Scheme for a product covered in the list under earlier PLI for Bulk Drug/KSM scheme? If yes, whether the Investment made then (after 1.4.2020) can be considered as eligible Investment?

As per Appendix A of the Operational Guidelines, under category-2, API/ KSM/ DI are eligible except for the 41 eligible products already covered under the "Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs)/ Active Pharmaceutical Ingredients (APIs) in India" notified by Department of Pharmaceuticals (DoP) vide Gazette Notification no.- 31026/16/2020-Policy, dated 21/07/2020 in Part-I, Section 1 of the Gazette of India (Extraordinary).

32. Clause 6.2.3 of the Operational guidelines provides that the plant, machinery and equipment of the project approved under the Scheme shall be used in regular course for manufacturing of goods under the eligible product categories. This does not preclude the usage of such machinery for manufacturing of other pharma goods. The applicant must submit a declaration about usage of machinery for each year during the period that such applicant is claiming incentive under the Scheme – In this context, following clarifications are sought a) in this scheme, Project is not approved but eligible products of the applicant would be approved – need to correct the same, b) format of aforesaid declaration is not provided in the operational guidelines

a) In clause 6.2.3, the word project refers to the eligible products under the scheme.

b) Respective format for the same would be made available to the applicants selected under the scheme as per the operational guidelines.

33. Clause 6.1.1. mentions that Investment made on or after April 1, 2020 is counted for the purpose of the Scheme. Appendix B mentions that the minimum cumulative investment per participant for first year (i.e. FY 2021-22) should be either Rs. 200/ 50/ 10 crore depending upon the Groups. Further, clause 7.1.1 states that the selected participants in the scheme will be eligible for incentives on incremental sales of eligible products based on yearly threshold criteria including minimum cumulative investment.

	Need clarification as to whether the minimum cumulative investment of FY 2021-22 should also include the investments, if any, made by the participant in 2020-21. This would help avoid confusion for the Trade. The eligibility criteria from the perspective of investment is minimum cumulative investment and not equivalent investment every year during the tenure. Therefore, the investment made on or after 1 April 2020 shall be considered for the investments to be made during FY 2021-22 or thereafter based on the amount invested. This logic should apply to all the subsequent years i.e. investment made in excess of minimum cumulative threshold for a year should be considered towards fulfilment of criteria for the next year. Should the eligible investment be restricted to a green field project? From the guidelines it does not appear to restrict to green field only, however confirmation on the same would help to have clarity for the applicants. Should there be a clear nexus between the investment and the incremental sale of eligible products? Whether goods manufactured from new investment only will be considered towards sale of eligible products / incentives thereof under the Scheme. The scheme is in relation to the eligible product and the there is no specific restriction to make an investment only in greenfield project. The eligible products being manufactured at any of the existing sites of the applicant can be considered subject to meeting other criteria. Further, Sl. No. 6 of the Quarterly Review Report requests for manufacturing locations of the selected applicant and not any approved manufacturing locations (there is no concept of approved manufacturing locations under the Scheme). Therefore, it appears that if the applicant can substantiate incremental sales of the eligible products from any of the manufacturing sites, the incentives shall be granted. Would require confirmation to this understanding.
	Investment done from 01.04.2020 to 31.03.2022 would be counted under cumulative investment for FY 2021-22. Applicant may choose to invest as per business requirements. Actual cumulative investment done by the applicant must meet the minimum cumulative investment criteria as defined in Appendix B of Operational guidelines, for being eligible for incentives Investment may be made in the existing plant or a new location, as per choice of the Applicant. However, Applicant has to provide information about all the locations where investment has been made in QRRs/ as otherwise instructed. Sl. No. 6 of the Quarterly Review Report for manufacturing locations of the selected applicant may be read as manufacturing locations of all approved eligible products of the Applicant. Sales of the eligible products would be considered from existing or new setups for the purpose of calculation of incentives.
34.	Clause 6.1.4 clarifies that the date of purchase invoice would be considered as the date of investment under the Scheme. Clause 6.1.5 provides that the heads of investment, based on which eligibility is being determined, should be capitalised in the books of accounts of the applicant as certified. Need confirmation that there is no requirement that the heads of investment should be capitalised in the same year of purchase invoice – even if the same is capitalised in subsequent years falling outside the Scheme period, the same will be considered as part of eligible investment per se.
	As per the scheme guidelines, to be considered as eligible investment, both invoice date and capitalization should be within the investment period under the scheme. With regard to minimum cumulative investment for a particular year, eligibility of investment will be based on the capitalization of the investment in the books of accounts in that year. Further, as per clause 6.1.5, expenditure on R&D, product registration may be in the nature of capital/ revenue expenditure where such is certified by the Statutory Auditor/ ICA. Therefore, expenditure in respect to R&D and product registration may also be included under the eligible investment in the year of expenditure.
35.	Clause 6.2.1 and Clause 6.2.4 inadvertently refers to clause 2.16.1 as compared to clause 2.15.1– this may be corrected
	Corrigendum/ Addendum dated 30.06.2021 has been issued by DoP regarding the same. The same is available on the website of the DoP/ SIDBI.

36. Concept of Successor-in-interest has been defined in clause 2.20. The same shall mean the new or re-organised entity formed after the merger, de-merger, acquisition, transfer of business or significant change in ownership of an applicant. Clause 12.1 provides that in case of change of shareholding pattern leading to a successor in interest then the same should be informed to PMA who would then inform DoP for approval from incentives perspective. Clause 12.3 provides that in case of a successor in interest, all investment undertaken by the applicant to whom the approval was accorded under the Scheme, would be considered for determining eligibility, subject to approval and compliance with any other condition stipulated by the DoP, as may be deemed appropriate.
Clarification is required as to whether in case of acquisition done in say 2020-21 or thereafter by an applicant for business having eligible products, the base sales turnover of 19-20 (period prior to acquisition) would be counted for computation of incremental sales as per clause 7.2.5. The said clause does not provide any restriction. Also whether acquisition made during the period of scheme would qualify for investment (given that it would value towards plant, machinery etc.)

The base year sales of FY 2019-20 of the acquired business would be taken as part of the base year sales of the Applicant.
As per clause 6.1.2 of the Operational guidelines, no second-hand machinery is allowed under the Scheme. The assets acquired as part of the acquisition would be used assets and therefore, are inadmissible as per the above Para.

37. As per para 6.1.2 of the guidelines, investment in second hand R&D equipment is ineligible. However, we understand that investment in new R&D equipment is eligible and covered under 2.15.1 and 2.15.2. Request you to please confirm the same.

The interpretation is correct.

38. Whether a company which has applied under the earlier PLI Scheme for API/KSM in 2020 but not selected then, can now apply under this 2021 PLI Scheme for a product covered in the list under earlier PLI for Bulk Drug/KSM scheme? If yes, whether the Investment made then (after 1.4.2020) can be considered as eligible Investment?

No, as the 41 items (APIs/ KSMs/ Dis) in the Bulk Drug PLI scheme have been excluded from the list of eligible products for this PLI Scheme.
Please refer to Appendix A of the Operational Guidelines.

39. Whether Investment of Rs. 1000 crore on a cumulative basis (minimum 200 crore per year) over a 5 year period up to FY 2025-26 is required to be made only by the applicant company on a standalone basis or such investment can be made by more than one Indian group companies (e.g. Indian parent and it's wholly owned Indian subsidiary) will be considered as an eligible investment?

Investment made in India, made only by the Applicant (and not by any Group Company) as per the eligibility given in clause 2.15 of the Operational Guidelines shall be considered while calculating incentives.

40. As Eligible investment: is made on or after April 01, 2020. In case of R&D Expenditure cases are there spend is spread over more than year for new products. In case of our existing products under development and selected under scheme whether R&D spend done before April 01,2020 eligible as Investment.

No. Only expenditure on R&D done after April 01, 2020 will be allowed for calculation of Eligible Investment under the Scheme.

41. The guidelines provide that all the non-creditable taxes and duties to be included in the expenditure for calculating the investment. Are the benefits derived from RODTEP scheme and PLI scheme mutually exclusive or both can be claimed simultaneously for the same products?

As per Clause 7.1.6 of the Operational Guidelines, eligibility under the Scheme shall not affect eligibility under any other scheme and vice versa.

H. Threshold/ Incremental Sales related FAQs

1. Whether P2P based product sales (Traded goods) in India to be included?

   As per the Operational Guidelines, P2P based product sales and any other trading revenue, will not be considered for threshold/ incremental sales at the time of calculation of incentive.

2. If an applicant meets the investment criteria only from R&D and uses CMO(s) for manufacturing, where the manufactured products are sold through the applicant, will such entity be eligible to apply for the scheme.

   Cumulative Investments under the scheme may be made only from eligible R&D expenditure as per clause. 2.15.2.

   Revenue from sale of eligible products produced under contract manufacturing shall not be considered for calculating threshold/ incremental sales. However, revenue from sale of eligible products produced under loan licensing manufacturing by applicant will be considered for calculating threshold/ incremental sales.

3. We would like to understand from your good office, whether the company having the license from CDSCO/ SLA to manufacture and sell the IVD devices can apply for PLI even to the extent of manufacturing carried out by the contract/ third party manufacturers, who does not have any specific license from CDSCO/ SLA to manufacture In-vitro Diagnostic devices?

   In case the sales of products manufactured under contract manufacturing is booked as manufacturing revenue in the books of accounts of the Applicant and Statutory Auditor's certificate is submitted by the applicant as per the Scheme, the same would be considered for calculating GMR.

   However, revenue from sale of eligible products produced under contract manufacturing shall not be considered for calculating threshold/ incremental sales at the time of claim of incentives, as per clause 2.16 of the Operational Guidelines.

4. Since a cumulative investment number would be given to the authorities, along with the list of products proposed to be manufactured, what would happen if the products' sales committed at the time of making the application is not achieved?

   Or in case out of 10 products committed at the time of making the application, only 8 are actually manufactured and sold. API prices generally fall - if there is 10 % growth in volume but 20 % degrowth in value. How to handle such situation which is common in API.

   No incentives would be given for the year in which sales are not achieved as per Appendix B of Operational Guidelines.

   Further, for incentive calculation, the aggregate sales of all the eligible products would be considered. However, data will be submitted by Applicants for sales of individual eligible products at the time of claim.

5. Clause 7.1.3 read with Appendix B– Whether average growth in sales would be required to be met for each product separately or for all the products applied for, taken together? For e.g. if for one product, a 9% growth is achieved and for the other product it is only 6%, the average growth for both products taken together is 7%. Would this suffice?

   The aggregate sales, during the year to which the claim pertains, of all the eligible products would be taken for incentive calculation. However, data will be submitted by Applicants for sales of individual eligible products at the time of claim.

6. Whether incremental manufacturing sales of related parties, where investment is made by the applicant, will be considered?

   Investments made in compliance to clause 2.15 and 6, in the books of accounts of the applicant, shall be considered under eligible investment.

   Incremental sales of all approved eligible product in respect of the applicant will be considered for incentive. Any sales from related party will not be considered for arriving at incremental sales.

7. In case in any of the year, the applicant company achieves 12% sales growth over previous year which is 5% above the threshold growth of 7% and in the next subsequent year, growth rate achieved is 5%.

Every year has a new threshold sales criterion as given in the Appendix B of the operational guidelines. In case, any applicant does not meet the criteria of threshold sales, the applicant will not be eligible for any incentive for that particular year.

8. In case the applicant cumulative CAGR is equal or higher than 7% (as compared to first year), though in one of the years, the growth is lower than 7%. Under this situation, the applicant company would be eligible for incentive in the year in which sales growth registered was 5% but CAGR equal or greater than 7% as compared to the first year?

No, CAGR is not a criterion for calculation of incentive.

9. What if the growth in a particular year is less than 7% (reason could be - pandemic, Price erosion etc)

As per the operational guidelines, if the Threshold/ Incremental sales as per Appendix B is not achieved by an Applicant in any given FY, that applicant will not be eligible for any incentive for that particular year.

10. For the purpose of determining eligibility of incentive for first year i.e. FY 22-23, the threshold sales in FY 22-23 for eligible products has to be greater than Rs. 50 Crore in case of a Group A participants. Does this Rs 50 Cr refer to incremental sales as compared to sales in the base year of FY19-20?

Whether the sales in FY 23 have to be computed in aggregate level to arrive at this minimum Rs.50 Crs threshold or it should be computed product wise?

The threshold sales of Rs. 50 cr. for FY 2022-23 does not mean incremental sales.

For subsequent financial years, i.e. FY 2023-24 onwards, the threshold sales shall be computed at 7% growth over actual sales of the previous FY for the approved eligible products.

Aggregate sales of all approved eligible products must be Rs. 50 Crore for Group A applicant for FY 2022-23.

12. For determination of Incentive eligibility whether threshold Sales of Rs. 50 crore for Eligible Products in FY 2022-23 is the aggregate sale of all the approved eligible products or the threshold to be achieved is for each of the approved & eligible product (i.e. Rs. 50 crore x No. of Products?

Aggregate sales of all approved eligible products must be Rs. 50 Crore for Group A applicant for FY 2022-23.

13. Base year of sales considered is 2019-20 and the first year wherein we would measure incremental sales is 2022-23; Whether DoP would measure the incremental sales directly comparing the sales of eligible products between 2019-20 and 2022-23 to verify whether the applicant met the criteria for incentive in the Year 1?

Aggregate sales of all approved eligible products must be Rs. 50 Crore (Group A)/ Rs. 10 crore (Group B)/ Rs. 1 crore (Group C)/ Rs. 50 lakh (Group C MSME) applicant for FY 2022-23.

Further, incentive calculation will be done in the following way, subject to achievement of Minimum Cumulative Investment and Threshold Sales (described above):

Incentive= (Sales of approved eligible products for FY 2022-23 minus Sales of those products in FY 2019-20) * Incentive Rate for the Product Category.

14. All New products would be having Nil revenue in 19-20 & hence would they be eligible for incentive on 100% of revenue if such products are falling in the given sub-categories. [New products being part of given sub-categories should be eligible on full sales value for the incentive.] If all the products are new products having sales from FY 21-22 onwards, will the incentive computation start as zero base year (FY 19-20) sales?

Yes. Base year sales i.e., for sales for FY 2019-20 in respect of the eligible products will be considered as zero in the instant case.

15. In case of acquired brands due to M&A; should the base sales be taken as NIL? [For M&A cases also, the acquired brands should be considered as new brand for the applicants.]

Base values of acquired brands will be taken into account for arriving at incremental sales.

16. What if there is a situation like Pandemic - resulting in less turnover and thus failure to achieve YOY growth.

These are very specific situations which may not happen frequently in the regular course of business. The Scheme will be implemented as per the Scheme guidelines.

17. If we are asked to make huge quantity of a drug where sales value is low or asked to do job work for other company. E.g. recently companies were forced to manufacture Remdesivir - how to handle?

This is a very specific situation which may not happen frequently in the regular course of business. The Scheme will be implemented as per the Scheme guidelines.

18. Clause 7.2.5 refers to baseline sales of the eligible product in 19-20. If there was no sales of eligible product in 19-20, can the same be factored as NIL for the purpose of computing incremental sales during a given financial year of the scheme.

Yes. In case there was no sales of eligible product in FY 2019-20, the base year sale will be considered as NIL.

19. For calculating the incremental sales as compared to the Base Year 2019-20, please confirm as to whether incremental sales of both Formulation and APIs of the eligible Products can be considered under the PLI Scheme of June 2021 or only incremental sales of Formulation would be considered?

Both can be considered if the products are eligible under the scheme and approved by the DoP.

20. Appendix B provides that for the purpose of determining eligibility of incentive for 2022-23, the threshold sales in FY 2022-23 for eligible products has to be greater than a specified amount depending upon the group of the applicant. Need clarify on whether the increase by Rs 50 crores is to be factored by comparing with base turnover of said eligible products in FY 19-20 or should the same be considered by comparing with sales of eligible products done in FY 21-22 (a year prior to FY 2022-23)

As per, Appendix B of the guidelines, For the purpose of determining eligibility of incentive for first year i.e. FY 2022-23, the threshold sales in FY 2022-23 for eligible products has to be greater than specified amount depending upon selected applicant's group. For example, for group A applicant the threshold sales of the first year i.e. for FY 2022-23 is Rs.50 Crore.

Further, incentive under the scheme shall be calculated on the incremental sales of the Eligible Product(s) approved to the participant, subject to meeting the criteria of threshold sales and minimum cumulative investment for the corresponding year, as given in the Appendix B of the guidelines.

Incremental sales mean sales of approved eligible products during a given Financial Year minus the baseline sales (FY 2019-20) of the eligible products.

For example, if sales from approved eligible products for the year 2022-23 is Rs. 60 Crore and the baseline sales of approved eligible product (FY 2019-20) is Rs. 20 crore, the incremental sales shall be Rs. 40 Crore.

21. Base year of sales considered is 2019-20 and the first year wherein we would measure incremental sales is 2022-23; hence, whether they would measure the incremental sales directly comparing the sales of eligible products between 2019-20 and 2022-23 to verify whether the applicant met the criteria for incentive in the Year 1?

Criteria for getting incentive in FY 2022-23 is:

Threshold sales in FY 2022-23 for all eligible products, taken together, to be greater than Rs. 50 crore in case of a Group A participant, greater than Rs.10 crore in case of a Group B participant, greater than Rs.1 crore in case of a Group C participant and greater than Rs. 50 Lakh in case of a Group C MSME participant.

Calculation of incentive would be based on Net Incremental Sales i.e: Actual net sales of eligible products in FY 2022-23 minus the net sales of eligible products in base year i.e. FY 2019-20.

22. For working out the amount of Incentive to an Applicant whether the sales of eligible products of Group companies of Applicant (e.g. Indian Parent and it's wholly owned subsidiary) is to be considered or sales of only Applicant company on a standalone basis is to be considered?

Sales of eligible products by only by the Applicant (and not by any Group Company) as per the eligibility given in clause 2.15 of the Operational Guidelines shall be considered while calculating incentives.

I. Claim for Incentive related FAQs

1. Clause 12.4 of the Guidelines states that in case of any proceedings under any Act leading to adjustment of pricing in the transactions between related parties, effect shall be given in calculation of incentive and/ or eligible committed investment. How will such adjustment be considered for calculation of incentive and/ or eligible committed investment? What impact would these have?

The adjustment would be considered subject to provisions of relevant statutes and Accounting Standards- 18 and corresponding Ind-AS, as amended from time to time.

2. Clause 7.2.5 of the Operational guidelines provides that incentive applicable to selected applicant shall be computed as "net incremental sales of eligible product Rate of Incentive– Assume that the company is already manufacturing the eligible product in base year 19-20 from existing plant and machinery and continues to use the same for manufacture and sale thereof. Further investment is done in new plant and machinery for the same eligible product, but commercial production and sales take place in the year 2023-24. Meanwhile incremental sales requirement for existing plant for the eligible product continues and there the threshold requirement is met. Will the same be counted towards incentives given that that there is net incremental sales of eligible product (even if the same is not manufactured from new plant and machinery for the same eligible products)

Yes, the interpretation is correct. However, year wise minimum cumulative investment criteria and incremental net sales criteria both have to be met by the Applicant as per Appendix B of the Operational guidelines.

3. In case the eligible products are added to list later on i.e say in FY 2023-24 for secrecy or any other reason. What happens to the investment in P&M or R&D spends done pre the said year? So basically question is whether investment is also to be seen qua the product list submitted by the applicant or qua eligible products specified in the guidelines only?

As per clause 7.2.2 of the operational guidelines, the selected applicant shall have the option to change the product mix approved to them not more than 5 times during the tenure of the scheme with the prior approval of the DoP.

Once the change in product mix is approved, eligible investment made towards P&M or R&D (as defined in clause 2.15 of the operational guidelines) in respect of the newly approved product, made after 01.04.2020 can be considered under the scheme.

4. (a) Whether incentive will be available for an eligible product, manufactured in FY 2023-24 for the first time, provided the same has been approved in the Application. That is, threshold sale in FY 2022-23 for the said new product will be NIL and also the sales in the base year (FY 2019-20) for the said product will be NIL.

(b) Also, if any eligible product which is not covered in Application but manufactured subsequently (say FY 2023-24), whether incentive will be available.

(a) As per the Operational Guidelines, the first year for release of incentive is FY 2022-23. In the instant case, the incremental sale for FY 2022-23 will be considered as zero. Hence, the applicant won't be eligible for any incentive in the FY 2022-23.

For FY 2023-24 (first year of manufacturing), the applicant may be eligible for incentive, subject to achievement of committed cumulative investment and threshold sales under the eligible product.

As per Appendix B of the Operational Guidelines:

"For the purpose of determining eligibility of incentive for first year i.e. FY 2022-23, the threshold sales in FY 2022-23 for eligible products has to be greater than Rs.50 crore in case of a Group A participant, greater than Rs.10 crore in case of a Group B participant, greater than Rs.1 crore in case of a Group C participant and greater than Rs. 50 Lakh in case of a Group C MSME participant.

For subsequent financial years i.e. from FY 2023-24 onwards, the threshold sales shall be computed at 7% growth over actual sales of the approved eligible product of the previous financial year."

In the instant case, the applicant does not have any sales under the eligible product in FY 2022-23. Hence, in line of the Operational Guidelines, the threshold sales for FY 2023-24 are to be considered at 7% growth over the first year's threshold sales (as defined in the scheme) of Rs.50 Crore/ Rs.10 Crore/ Rs.1 Crore depending on the applicant's group. For subsequent years, the threshold sales shall be computed at 7% growth over actual sales.

(b) Yes.

As per clause 7.2.2 of the Operational Guidelines, the selected applicant shall have the option to change the product mix approved to them during the tenure of the scheme with the prior approval of the DoP. However, this option may be exercised not more than 5 times during the tenure of the Scheme.

5. Clause 2.8 and 2.15 - Whether committed investment can be made in a related party/ new subsidiary and the incentive be claimed at the applicant entity level, basis consolidated revenue achieved by the applicant company?

No. As per the Operational Guidelines, both committed investment and threshold/ incremental sales must be achieved by Applicant only and should be reflected in standalone Financial Statements of the Applicant.

6. Can R&D expenditure made towards eligible products, which the applicant is not eventually able to sell during the tenure of the scheme, would be considered as eligible investment?

To be eligible for incentives, the applicant has to achieve both the Minimum Cumulative Investment and Threshold/ Incremental Sales as per Appendix B of the Operational Guidelines.

7. Is there any maximum limit of incentive which will be paid out in any year to an applicant? Or to all applicants in a Group?

The annual incentive allocation, vide clause 7.2 of the Operational Guidelines, shall be made for each participant by DoP within the total incentive allocation per participant fixed for the entire tenure of the scheme as stated in the approval letter. The participant shall be eligible to draw incentive within that annual allocation.

8. If we are making basket ABC and then if we will make basket XYZ where top line and bottom line are different - How will such aberrations be handled?

For being eligible for the incentive, the applicants have to meet threshold sales under the approved eligible products and minimum cumulative investments as per Appendix B. Further, the scheme also has a provision for change in eligible product subject to approval of DoP.

9. After submission of the documents in how many days incentive will be remitted?

Incentive will be released after careful examination of the claim application submitted by the selected applicant by the PMA and approval of DoP thereof.

10. As per clause 9.6 of the operational guidelines, the bank guarantee shall be released upon achievement of minimum cumulative investment for FY 2021-22 and invoked in case of FY 2021-22 is not achieved unless explicit permission is given by DoP. Are there any consequences if the Company fails to achieve the same in the subsequent years, other than losing out on the particular year incentives?

Clause 9.8 provides that if a selected applicant is found to be ineligible at any stage, or if it has not complied with notifications, orders, guidelines etc of the Scheme, or declines the offer of the approval under the Scheme at any stage, the envisaged incentive claim of such selected applicant shall be forfeited and the bank guarantee shall be invoked, if not released under para 9.6 and the offer letter issued shall stand cancelled. Need clarification on what would be covered under 'if it has not complied with notifications, orders, guidelines etc of the Scheme' – would not completing minimum cumulative investment in any subsequent year (after FY 2021-22) come under this reference.

As per clause 9.6 of the operational guidelines, the bank guarantee shall be released upon achievement of threshold investment of FY 2021-22 and shall be invoked in case of non-achievement of minimum cumulative investment of FY 2021-22.

If the selected applicant fails to achieve minimum cumulative investment (as defined in the Appendix B) in the subsequent years, it will not be eligible for incentive for that particular year.
Clause 9.8 states that applicants found to be ineligible at any stage, or if it has not complied with notifications, orders, guidelines etc. of the Scheme, or declines the offer of the approval under the Scheme at any stage, for any reason. As such, clause 9.8 is not related to achievement/ non- achievement of minimum cumulative investment in any given year under the scheme.

11. A company which has applied under the earlier PLI Scheme for API/ KSM in 2020 but was not selected for whatever reasons. However, one of such APIs does flow into the formulation and gets covered under the eligible Product list under the new PLI Scheme of June 2021. In this case, whether the investment made in the API site to create such API capacity can be considered for calculating the Rs. 200 Crs per year investment from the Base Year (after 1-04-2020) as defined in this PLI Scheme of June 2021? For calculating the incremental sales as compared to the Base Year 2019-20, please confirm as to whether incremental sales of both Formulation and APIs of the eligible Products can be considered under the PLI Scheme of June 2021 or only incremental sales of Formulation would be considered?

Investment- If the API plant is being used in regular course of action for making API, which is being consumed for making the eligible product under the scheme, it could be considered as eligible investment under the Scheme.
Sales- Only net incremental sales for eligible products would be considered.

12. Availment of complete incentive in a single year: Can an applicant invest the entire amount in a single financial year? If yes can such applicant avail the entire incentive permissible under the scheme per participant in the same year based on the incremental sales achieved?

Applicant may choose to invest as per business requirements either in stages or one go. Actual cumulative investment done by the applicant must meet the minimum cumulative investment criteria as defined in Appendix B of Operational Guidelines, for being eligible for incentives.
However, incentive can be claimed as per Appendix B Schedule and not at one go.

13. Group B applicant make investment as per limits prescribed for Group A: Can an applicant who is categorized as a Group B applicant as per the GMR, make an investment of INR 1000 crores and be eligible to claim maximum incentive of INR 1200 crores which is applicable to Group A participants.

There is only the threshold which is prescribed for investment and no ceiling has been prescribed. Group B applicant may make an investment of Rs. 1000 crore, but maximum incentive ceiling for a Group B applicant is Rs.300 crore over the entire Scheme.

14. For disbursement of incentives no timeline mentioned with regard to approval from DoP, though PMA processes the application for claim within 60 days of receipt of application.

As per clause 7.3.7 of the Operational Guidelines, the PMA shall process claim for disbursement of incentive within 60 days from the date of receipt of such claim and make appropriate recommendations to DoP. Disbursement of the incentive will be done subsequently.

15. As per para 9.6 of the operational guidelines, the bank guarantee shall be released upon achievement of minimum cumulative investment for FY 2021-22. What could be the possible consequences if the Company fails to achieve the same in the subsequent years?

As per clause 9.6 of the operational guidelines, bank guarantee shall be revoked in case the minimum cumulative investment for FY 2021-22 is not met. However, no specific penalty has been prescribed currently for failure to meet the subsequent investments. If committed investment criteria is not met in any year, incentive for that year shall not be granted. However, the applicant will not be restricted from claiming incentive for subsequent years, provided criteria of minimum cumulative investment and incremental sales are met for such subsequent years.

J. Miscellaneous FAQs

1.	What if a product comes under price control and sales value is drastically reduced (formulations)?
	There is no such provision in the Operational Guidelines for the same.
2.	The scheme has provisions around succession-in-interest, we request for clarification on how the new investment shall be calculated and PLI shall be disbursed to the entities formed after demerger of the undertaking as incremental investments and production shall be done in the two entities.
	As per clause 12.3 of the operational guidelines, in case of a successor-in-interest, all Investment undertaken by the applicant to whom approval was accorded under the Scheme, would be considered for determining eligibility, subject to approval and compliance with any other condition stipulated by the DoP, as may be deemed appropriate. Cases of merger/ demergers are not events of normal course of business. Hence, such specific cases may be treated on case-to-case basis subsequent to the event which would depend upon the approval by DoP and compliance of conditions stipulated by the DoP on the case specific approval.
3.	Clause 3 says Tenure of the Scheme is from FY 20-21 to FY 28-29. While 20-21 may have been factored as the investment of this year is also counted, but not sure why FY 28-29 is factored when the incentive period is 6 years from FY 22-23 to FY 27-28
	As per clause 7.3.3 of the operational guidelines, claims for disbursement of incentive shall be filed along with supporting documents within one month of the closure of the given financial year. If the claim is found to be in order, 75% of it shall be released and the remaining 25% shall be released after submission of final audited accounts of the Company. Accordingly, incentive claim for FY 2027-28 will be submitted by the applicant and processed by PMA/ DoP in FY 2028-29. Hence the tenure of the scheme is from Financial Year 2020-21 to Financial Year 2028-29.

Department of Pharmaceuticals

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Invitation of Applications under the Production Linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of Critical Key Starting Materials (KSMs)/ Drug Intermediates and Active Pharmaceutical Ingredients (APIs) in the Country - reg.

Notice No.31026/16/2020-Policy/Scheme, dated 2nd July, 2021

1. In continuation to this Department's Notice of even number dated 30.04.2021 and 14'" June, 2021 on the subject mentioned above, applications are also invited for the following eligible product:

Sr. No.	Target Segment	Name of Eligible Product	Minimum Annual Production Capacity as per Scheme Guidelines (in MT)	Shortfall in Minimum Annual Production Capacity (in MT)	Maximum no. of applicants to be selected
	I - Key Fermentation Based KSMs / Drug Intermediates	Erythromycin Thiocynate (TIOC)	800	1600	2

2. The other terms and conditions of Notice dated 30.04.2021 shall remain unchanged.

N.K. Joshi, Under Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Shastri Bhawan, New Delhi.

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Ceiling/Retail Price for Amphotericin B (Emulsion) Injection 50 mg - reg.

Office Memorandum, 05th July 2021

1. This matter relating to fixation of retail price of Amphotericin B (Emulsion) Injection 50 mg was deliberated upon in the 89th meeting of the Authority held on 28.06.2021 in which it was decided that the 'ceiling price as applicable for Amphotericin B (Lipid) Powder for Injection 50 mg is also applicable for Amphotericin B (Emulsion) injection having the same dosage form and strength.'

2. Accordingly, the undersigned is directed to state that the ceiling price and provisions of DPCO 2013 as extended for Amphotericin B (Lipid) Powder for Injection 50 mg would also be applicable for the formulation Amphotericin B (Emulsion) injection having the same dosage form and strength.

F.No.19 (2383)/2021/DP/Div.II/NPPA

Rashmi Tahiliani,
Joint Director (Pricing),
National Pharmaceutical Pricing Authority,
Ministry of Chemicals & Fertilizers,
Department of Pharmaceuticals,
New Delhi.

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Enlistment under Appendix 2-E of M/s. Oriental Chamber of Commerce and Industry authorized to issue Certificate of Origin (Non-Preferential) - reg.

Public Notice No.11/2015-2020, dated 1st July, 2021

1. In exercise of powers conferred under paragraph 2.04 of the Foreign Trade Policy 2015 2020, the Director General of Foreign Trade hereby authorizes the following agency to issue Certificate of Origin (Non Preferential):

M/s. Oriental Chamber of Commerce and Industry,
Plot No. 11, above Kotak Mahindra Bank, Indira Nagar, Mandideep- 462046, Dist. Raisen
Tel. no.: 9827622438, 9893981916
E-mail : occimdp@gmail.com

2. Accordingly, name of the above agency is added at Serial No.07 (Madhya Pradesh/ Chhatisgarh) of Appendix 2E [List of Agencies Authorized to issue Certificate of Origin (Non Preferential)] to Appendices & Aayat Niryat Forms of FTP (2015-2020).

3. Effect of this Public Notice: M/s. Oriental Chamber of Commerce and Industry is enlisted under Appendix 2E of FTP, 2015-2020 for issuing Certificate of Origin (Non-Preferential).

F. No.01/93/180/41/AM-20/PC.II(B)/E-23705]

Amit Yadav,
Director General of Foreign Trade & Ex-officio Addl. Secretary, Directorate General of Foreign Trade,
Udyog Bhawan,
Ministry of Commerce & Industry,
Department of Commerce,
New Delhi.

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GOVERNMENT PRESS RELEASE

Rashtrapati Bhavan : Council of Ministers Portfolios - reg.

PRESS COMMUNIQUE

The President of India, as advised by the Prime Minister, has directed the allocation of portfolios among the following members of the Council of Ministers :-

Shri Narendra Modi	**Prime Minister** and also in-charge of: Ministry of Personnel, Public Grievances and Pensions; Department of Atomic Energy; Department of Space; All important policy issues; and All other portfolios not allocated to any Minister

CABINET MINISTERS

1.	Shri Raj Nath Singh	Minister of Defence
2.	Shri Amit Shah	Minister of Home Affairs; and Minister of Cooperation
3.	Shri Nitin Jairam Gadkari	Minister of Road Transport and Highways
4.	Smt. Nirmala Sitharaman	Minister of Finance; and Minister of Corporate Affairs
5.	Shri Narendra Singh Tomar	Minister of Agriculture and Farmers Welfare
6.	Dr. Subrahmanyam Jaishankar	Minister of External Affairs
7.	Shri Arjun Munda	Minister of Tribal Affairs
8.	Smt. Smriti Zubin Irani	Minister of Women and Child Development

Contd….2/-

CABINET MINISTERS (CONTD.)

9.	Shri Piyush Goyal	Minister of Commerce and Industry; Minister of Consumer Affairs, Food and Public Distribution; and Minister of Textiles
10.	Shri Dharmendra Pradhan	Minister of Education; and Minister of Skill Development and Entrepreneurship
11.	Shri Pralhad Joshi	Minister of Parliamentary Affairs; Minister of Coal; and Minister of Mines
12.	Shri Narayan Tatu Rane	Minister of Micro, Small and Medium Enterprises
13.	Shri Sarbananda Sonowal	Minister of Ports, Shipping and Waterways; and Minister of AYUSH
14.	Shri Mukhtar Abbas Naqvi	Minister of Minority Affairs
15.	Dr. Virendra Kumar	Minister of Social Justice and Empowerment
16.	Shri Giriraj Singh	Minister of Rural Development; and Minister of Panchayati Raj
17.	Shri Jyotiraditya M. Scindia	Minister of Civil Aviation
18.	Shri Ramchandra Prasad Singh	Minister of Steel
19.	Shri Ashwini Vaishnaw	Minister of Railways; Minister of Communications; and Minister of Electronics and Information Technology

Contd….3/-

CABINET MINISTERS (CONTD.)

20.	Shri Pashu Pati Kumar Paras	Minister of Food Processing Industries
21.	Shri Gajendra Singh Shekhawat	Minister of Jal Shakti
22.	Shri Kiren Rijiju	Minister of Law and Justice
23.	Shri Raj Kumar Singh	Minister of Power; and Minister of New and Renewable Energy
24.	Shri Hardeep Singh Puri	Minister of Petroleum and Natural Gas; and Minister of Housing and Urban Affairs
25.	Shri Mansukh Mandaviya	Minister of Health and Family Welfare; and Minister of Chemicals and Fertilizers
26.	Shri Bhupender Yadav	Minister of Environment, Forest and Climate Change; and Minister of Labour and Employment
27.	Dr. Mahendra Nath Pandey	Minister of Heavy Industries
28.	Shri Parshottam Rupala	Minister of Fisheries, Animal Husbandry and Dairying
29.	Shri G. Kishan Reddy	Minister of Culture; Minister of Tourism; and Minister of Development of North Eastern Region
30.	Shri Anurag Singh Thakur	Minister of Information and Broadcasting; and Minister of Youth Affairs and Sports

Contd….4/-

MINISTERS OF STATE (INDEPENDENT CHARGE)

1.	Rao Inderjit Singh	Minister of State (Independent Charge) of the Ministry of Statistics and Programme Implementation; Minister of State (Independent Charge) of the Ministry of Planning; and Minister of State in the Ministry of Corporate Affairs
2.	Dr. Jitendra Singh	Minister of State (Independent Charge) of the Ministry of Science and Technology; Minister of State (Independent Charge) of the Ministry of Earth Sciences; Minister of State in the Prime Minister's Office; Minister of State in the Ministry of Personnel, Public Grievances and Pensions; Minister of State in the Department of Atomic Energy; and Minister of State in the Department of Space

MINISTERS OF STATE

1.	Shri Shripad Yesso Naik	Minister of State in the Ministry of Ports, Shipping and Waterways; and Minister of State in the Ministry of Tourism
2.	Shri Faggansingh Kulaste	Minister of State in the Ministry of Steel; and Minister of State in the Ministry of Rural Development

Contd…..5/-

MINISTERS OF STATE (CONTD.)

3.	Shri Prahalad Singh Patel	Minister of State in the Ministry of Jal Shakti; and Minister of State in the Ministry of Food Processing Industries
4.	Shri Ashwini Kumar Choubey	Minister of State in the Ministry of Consumer Affairs, Food and Public Distribution; and Minister of State in the Ministry of Environment, Forest and Climate Change
5.	Shri Arjun Ram Meghwal	Minister of State in the Ministry of Parliamentary Affairs; and Minister of State in the Ministry of Culture
6.	General (Retd.) V. K. Singh	Minister of State in the Ministry of Road Transport and Highways; and Minister of State in the Ministry of Civil Aviation
7.	Shri Krishan Pal	Minister of State in the Ministry of Power; and Minister of State in the Ministry of Heavy Industries
8.	Shri Danve Raosaheb Dadarao	Minister of State in the Ministry of Railways; Minister of State in the Ministry of Coal; and Minister of State in the Ministry of Mines
9.	Shri Ramdas Athawale	Minister of State in the Ministry of Social Justice and Empowerment
10.	Sadhvi Niranjan Jyoti	Minister of State in the Ministry of Consumer Affairs, Food and Public Distribution; and Minister of State in the Ministry of Rural Development
11.	Dr. Sanjeev Kumar Balyan	Minister of State in the Ministry of Fisheries, Animal Husbandry and Dairying

Contd…..6/-

MINISTERS OF STATE (CONTD.)

12.	Shri Nityanand Rai	Minister of State in the Ministry of Home Affairs
13.	Shri Pankaj Chaowdhary	Minister of State in the Ministry of Finance
14.	Smt. Anupriya Singh Patel	Minister of State in the Ministry of Commerce and Industry
15.	Prof. S. P. Singh Baghel	Minister of State in the Ministry of Law and Justice
16.	Shri Rajeev Chandrasekhar	Minister of State in the Ministry of Skill Development and Entrepreneurship; and Minister of State in the Ministry of Electronics and Information Technology
17.	Sushri Shobha Karandlaje	Minister of State in the Ministry of Agriculture and Farmers Welfare
18.	Shri Bhanu Pratap Singh Verma	Minister of State in the Ministry of Micro, Small and Medium Enterprises
19.	Smt. Darshana Vikram Jardosh	Minister of State in the Ministry of Textiles; and Minister of State in the Ministry of Railways
20.	Shri V. Muraleedharan	Minister of State in the Ministry of External Affairs; and Minister of State in the Ministry of Parliamentary Affairs
21.	Smt. Meenakashi Lekhi	Minister of State in the Ministry of External Affairs; and Minister of State in the Ministry of Culture
22.	Shri Som Parkash	Minister of State in the Ministry of Commerce and Industry

Contd…..7/-

MINISTERS OF STATE (CONTD.)

23.	Smt. Renuka Singh Saruta	Minister of State in the Ministry of Tribal Affairs
24.	Shri Rameswar Teli	Minister of State in the Ministry of Petroleum and Natural Gas; and Minister of State in the Ministry of Labour and Employment
25.	Shri Kailash Choudhary	Minister of State in the Ministry of Agriculture and Farmers Welfare
26.	Smt. Annpurna Devi	Minister of State in the Ministry of Education
27.	Shri A. Narayanaswamy	Minister of State in the Ministry of Social Justice and Empowerment
28.	Shri Kaushal Kishore	Minister of State in the Ministry of Housing and Urban Affairs
29.	Shri Ajay Bhatt	Minister of State in the Ministry of Defence; and Minister of State in the Ministry of Tourism
30.	Shri B. L. Verma	Minister of State in the Ministry of Development of North Eastern Region; and Minister of State in the Ministry of Cooperation
31.	Shri Ajay Kumar	Minister of State in the Ministry of Home Affairs
32.	Shri Devusinh Chauhan	Minister of State in the Ministry of Communications

Contd…..8/-

MINISTERS OF STATE (CONTD.)

33.	Shri Bhagwanth Khuba	Minister of State in the Ministry of New and Renewable Energy; and Minister of State in the Ministry of Chemicals and Fertilizers
34.	Shri Kapil Moreshwar Patil	Minister of State in the Ministry of Panchayati Raj
35.	Sushri Pratima Bhoumik	Minister of State in the Ministry of Social Justice and Empowerment
36.	Dr. Subhas Sarkar	Minister of State in the Ministry of Education
37.	Dr. Bhagwat Kishanrao Karad	Minister of State in the Ministry of Finance
38.	Dr. Rajkumar Ranjan Singh	Minister of State in the Ministry of External Affairs; and Minister of State in the Ministry of Education
39.	Dr. Bharati Pravin Pawar	Minister of State in the Ministry of Health and Family Welfare
40.	Shri Bishweswar Tudu	Minister of State in the Ministry of Tribal Affairs; and Minister of State in the Ministry of Jal Shakti
41.	Shri Shantanu Thakur	Minister of State in the Ministry of Ports, Shipping and Waterways
42.	Dr. Munjapara Mahendrabhai	Minister of State in the Ministry of Women and Child Development; and Minister of State in the Ministry of AYUSH
43.	Shri John Barla	Minister of State in the Ministry of Minority Affairs

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MINISTERS OF STATE (CONTD.)

44.	Dr. L. Murugan	Minister of State in the Ministry of Fisheries, Animal Husbandry and Dairying; and Minister of State in the Ministry of Information and Broadcasting
45.	Shri Nisith Pramanik	Minister of State in the Ministry of Home Affairs; and Minister of State in the Ministry of Youth Affairs and Sports

For immediate release.

(Ajay Kumar Singh)
Press Secretary to the President
07.07.2021

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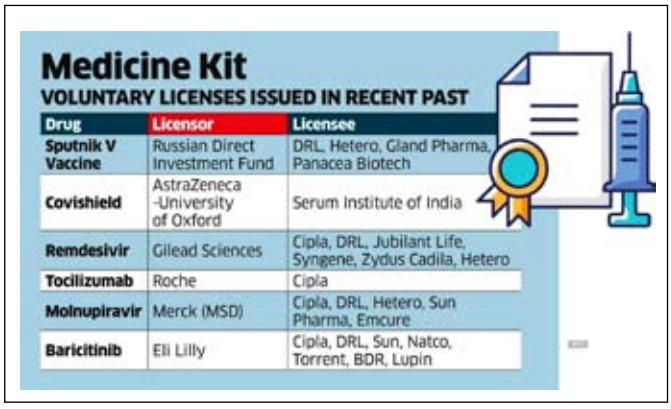
Local firms got voluntary licence for more drugs during pandemic

Govt did not have to issue compulsory licences for some Covid drugs that were in demand

Since the outbreak of Covid-19 last year, Indian drug manufacturers have launched a record number of patented drugs despite the country not issuing any compulsory licence, thanks to the voluntary licensing system.

Besides Covid-19 vaccines Covishield and Sputnik V, five patented drugs have been launched in the country through voluntary licence deals with original patent holders for their manufacturing and marketing. These include remdesivir by Gilead Sciences, baricitinib by Eli Lilly, tocilizumab by Roche, molnupiravir by Merck, and a Covid-19 tablet by Ennaid Therapeutics.

A voluntary licence (VL) is an authorisation given by the patent holder to a generic company to produce a patented drug while a compulsory licence (CL) is granted by the Controller General of Patents without the consent of the patentee.



"In the current pandemic scenario, voluntary licensing makes more prudent business sense as most of patentees lack resources in India to scale up production to meet exponentially growing demand of drugs that are critical to Covid-19 treatment," said Varun Chhonkar, founder of intellectual property research and advisory firm ipfeathers.

Not only has voluntary licensing helped bring innovative drugs to the country, but also their prices are between 50% and up to more than 99% less than the original brands as Indian drugmakers have the advantage of cheap production.

Natco, for example, has launched 4 mg tablets of baricitinib under the brand Barinat at ₹30 apiece, less than 1% of ₹3,230 per tablet price of US major Eli Lilly's original patented brand Olumiant. India's Patents Act of 2005 provides for the issue of CL in a public health emergency.

But the country has so far issued only one CL -- to Natco Pharma in 2012 for the generic production of Bayer Corporation's Nexavar, a life-saving medicine used for treating liver and kidney cancer. "The Patent Act provides that a request for voluntary licence should be made prior to applying or compulsory licence," said Gopakumar Nair, a Mumbai-based lawyer specialising on intellectual property, patent, and trademark issues. "Now that voluntary licences are being granted on almost every new drug, the need for seeking CL appears redundant in changing times," he said.

Technically qualified Indian drug makers following global regulatory and IP practices are receiving VLs without having to go for CLs, Nair said. Eli Lilly, for example, issued royalty-free, non-exclusive voluntary licences to manufacture and distribute baricitinib in the country to seven Indian companies - Cipla, Lupin, Sun Pharmaceutical, Dr Reddy's, MSN Laboratories, Torrent Pharmaceuticals and and Natco Pharma.

Yet, the government has often faced flak from social activist groups for its reluctance to issue compulsory licences.

Source : Raghu Balakrishnan, Economic Times, 02.07.2021

Zydus Cadila jab shows 66.6% efficacy, seeks regulatory nod

Zydus Cadila managing director Sharvil Patel. **(Photo: Reuters)**

Zydus Cadila said if the vaccine gets emergency use authorization from the DGCI, it could begin manufacturing in 45-60 days and scale production up to 10 million doses a month later

Drugmaker Zydus Cadila on Thursday applied for regulatory approval for ZyCoV-D, India's second indigenously developed covid-19 vaccine after Bharat Biotech's Covaxin.

Early analysis showed an efficacy of 66.6% for the three-dose vaccine, the Ahmedabad-based company said, adding it is "safe and very well tolerated" among 12-18-year-olds and works against the delta variant of SARS-CoV-2.

The company said if the vaccine gets emergency use authorization from the Drugs Controller General of India, it could begin manufacturing in 45-60 days and scale production up to 10 million doses a month later.

"Our target is to produce 100-120 million vaccine doses in a year. We can start from mid-August to have a run rate of around 10 million doses per month. A new facility to manufacture this vaccine will come up by the end of July, which will start producing ZyCoV-D at scale," managing director Sharvil Patel said in a virtual press conference.

ZyCoV-D is the world's first plasmid DNA vaccine, which produces the SARS-CoV-2 virus's spike protein in the body, triggering an immune response. If it gets emergency approval, ZyCoV-D will be India's fifth vaccine in the fight against covid-19, after Covishield, Covaxin, Sputnik V and Moderna's mRNA-1273 vaccine.

Zydus Cadila has invested ₹400-500 crore in developing its vaccine candidate. It is not looking at exports in the near term as it does not have sufficient quantities to supply other countries.

The company did not disclose the price of its vaccine. "We are only currently focusing our efforts on making sure we can make these doses available for India. It is too early to talk about pricing. We have not stockpiled any doses currently, and we will announce it before the commercial launch," Patel said.

The company said it submitted all the required data to the authorities.

"No moderate case of covid-19 was observed in the vaccine arm post-administration of the third dose, suggesting 100% efficacy for moderate disease. No severe cases or deaths due to covid-19 occurred in the vaccine arm after administration of the second dose of the vaccine," the company said in a statement.

Zydus Cadila claimed to have conducted the largest clinical trial for its covid-19 vaccine in India so far in more than 50 centres.

This was also the first time that any covid-19 vaccine had been tested in the 12-18 years age group in India, the company said.

Around 1,000 subjects were enrolled in this age group, and the vaccine was found to be safe and very well-tolerated. The tolerability profile was similar to that seen in the adult population, the company said.

"As the first-ever plasmid DNA vaccine for human use, ZyCoV-D has proven its safety and efficacy profile in our fight against covid-19. The vaccine, when approved, will help not only adults but also adolescents in the 12-18 years age group," Patel said.

The company has also evaluated a two-dose regimen for ZyCoV-D vaccine using a 3mg dose per visit, and the immunogenicity results had been found to be equivalent to the current three-dose regimen.

This will further help in reducing the full-course duration of vaccination while maintaining the high safety profile of the vaccine in the future.

Zydus Cadila acknowledged the support of the National Biopharma Mission, Biotechnology Industry Research Assistance Council, the Department of Biotechnology, the National Institute of Virology, the Indian Council of Medical Research and PharmaJet in the development of ZyCoV-D.

"ZyCoV-D had already exhibited robust immunogenicity and tolerability and safety profile in the adaptive phase I/II clinical trials carried out earlier. Both the phase I/II and phase III clinical trials have been monitored by an independent Data Safety Monitoring Board," the company said, adding that the plug-and-play technology on which the plasmid DNA platform is based is ideally suited for dealing with covid-19 as it can be easily adapted to deal with mutations in the virus, such as those already occurring.

Source : Neetu Chandra Sharma, HT Mint, 02.07.2021

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Laurus Labs gets DRDO licence to make anti-COVID drug 2DG

Drugmaker Laurus Labs has received licence from Defence Research and Development Organisation (DRDO) to manufacture and market 2-Deoxy-D-Glucose (2DG), an oral drug indicated as an adjunct therapy for hospitalised COVID-19 patients.

Announcing this, the company said it has already applied for emergency use authorisation for the product with the Central Drugs Standard Control Organization. The Drugs Controller General of India (DCGI) had on May 1 accorded emergency approval for use of 2DG on COVID-19 patients.

Laurus Labs is among a clutch of companies that have been issued licence to manufacture and market 2-DG, sources said. DRDO had last month invited expression of interest, from pharma companies, offering transfer of technology of the process for manufacturing 2-DG.

Developed by DRDO lab INMAS (Institute of Nuclear Medicine and Allied Sciences), the product during clinical trial showed that the molecule helps in faster recovery of hospitalised patients and reduces supplemental oxygen dependence. An official release, issued at the time of DCGI approval, said being a generic molecule and analogue of glucose, 2-DG can be easily produced and made available in plenty in the country.

Dr. Reddy's Laboratories in association with INMAS became the first company to roll out 2-DG. The Hyderabad-based pharma major earlier this week had announced the commercial launch of 2-DG, with the maximum retail price fixed at 990 per sachet. The company had said it will be supplied at a subsidised rate to government institutions. Last week, Shilpa Medicare had also announced receipt of an in-principle approval from DRDO for manufacture and sale of 2DG.

Like Shilpa Medicare, Laurus Labs too did not specify the time frame by when it intends to launch 2DG and the price it will set for the product.

Source : The Hindu, 02.07.2021

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Drug regulator NPPA approves price increase of 50% for carbamazepine, ranitidine, ibuprofen

The national drug pricing regulator (NPPA) on Friday said it has allowed a one-time increase of 50 per cent in the ceiling prices of nine scheduled formulations of three drugs - carbamazepine, ranitidine and ibuprofen - to ensure their availability.

These drugs are used as the first line of treatment and are important to the public health programme of the country, the National Pharmaceutical Pricing Authority (NPPA) said in its order.

NPPA, in its meeting on June 28, deliberated upon the case of upward price revision of the formulations of these drugs under Para 19 of DPCO 2013 and noted that the scheduled formulations being considered for upward price revision are low-priced drugs and have been under repeated price controls, it added.

DPCO 2013 is the Drugs (Prices Control) Order, 2013.

While carbamazepine is a anti-epileptic drug, ranitidine is used for the treatment of ulcers of the stomach and intestines and to prevent intestinal ulcers from coming back after they have healed. Ibuprofen is used to relieve pain from various conditions such as headache, dental pain, menstrual cramps, muscle aches, or arthritis.

The National Pharmaceutical Pricing Authority (NPPA) said it is of the considered view that unviability of these formulations should not lead to a situation, where these drugs become unavailable in the market and the public is forced to switch to costly alternatives.

To address the situation arising due to repeated price control, a one-time price increase of 50 per cent from the current ceiling price is being considered in public interest as an exceptional measure as advised by the Standing Committee on Affordable Medicines and Health Products (SCAMHP), NPPA said.

Accordingly, "NPPA invokes extraordinary powers in public interest under Para 19 of DPCO 2013 for upward revision of the ceiling prices of the nine scheduled formulations of 3 drugs by giving one time increase of 50 percent from the present ceiling price," it added.

The regulator was constituted as an independent regulator for pricing of drugs and to ensure availability and accessibility of medicines at affordable prices.

NPPA provides ceiling price to all drugs notified under Schedule-1 of the DPCO 2013, and monitors annual price increase for these and the non-scheduled drugs.

Source: Free Press Journal, 03.07.2021

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Third Vaccine Testing Lab to come up in Hyderabad

Hyderabad: A third Vaccine Testing Centre (VTC) in the country is expected to start in a month at the Hyderabad-based National Institute of Animal Biotechnology (NIAB).

According to Union Minister of State for Home Affairs G Kishan Reddy, Prime Minister Narendra Modi had sanctioned funds from the PM CARES for establishing the vaccine testing laboratory. He said that the Covid-19 pandemic has brought with it a lot of challenges. The Union government has taken several effective and timely steps to address these challenges. One such step was the ambitious mission to develop India's own vaccination for Covid-19.

The scientists and the researchers displayed exemplary commitment in developing India's own cost-effective vaccine in a short time which has helped in saving many precious lives, he said. He said this increased focus on vaccine production and necessitated the requirement of more vaccine testing centres. Currently, there are two VTLs in the country, the Central Drug Laboratory (CDL) situated at Kasauli in Himachal Pradesh, and the National Institute of Biologicals (NIB) located in Noida.

Now funds have been released for establishing two more VTLs, one at the National Centre for Cell Science (NCCS), Pune and the other one at the NIAB, Hyderabad, he said. The commencement of operations of the VTL at Hyderabad is expected in a month. "Hyderabad is home to many big pharma companies, Covid-19 vaccine production companies and the concerned R&D institution. Setting up the VTL at Hyderabad is a big step forward towards the comprehensive development of this sector which will also boost the production of Covid-19 vaccines," he added. The NIAB is engaged in the cutting-edge areas of biotechnology for improving health and productivity.

Source: Hans News Service, 04.07.2021

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Nine European nations issue 'Green Pass' to Covishield jab

A day after India flexed its muscle over discriminatory practice by the European Union with regard to Indian vaccines Covishield and Covaxin, nine EU countries gave their approval to the AstraZeneca vaccine for a "green pass", allowing free travel in the region of those vaccinated with Covishield. These nine countries are Austria, Germany, Slovenia, Greece, Iceland, Ireland, Spain, Estonia and Switzerland while more EU countries are expected to join in.

The European Union Digital Covid Certificate framework, or the Green Pass, to facilitate free movement during the Covid pandemic, came into effect on July 1 under which persons vaccinated with vaccines authorised by the European Medicines Agency (EMA) will be exempt from travel restrictions within the EU.

Individual member states have the flexibility to accept vaccines that have been authorised at the national level or by the World Health Organisation. However, while Astra Zeneca's Vaxzevria is approved by EU, the fate of its Indian version Covishield remains under suspense as the EMA has approved only four vaccines so far — Pfizer-BioNTech's Comirnaty, Moderna's Covid vaccine, the AstraZeneca shot manufactured and sold in Europe as Vaxzervria, and Johnson & Johnson's Janssen.

India has already asked the EU member countries to individually consider allowing Indians who have taken Covishield and Covaxin vaccines and want to travel to Europe.

There has been apprehension in India that people who took Covishield and Covaxin jabs are unlikely to be eligible for travel to the European Union member states under its "Green Pass" scheme. The EU Digital Covid certificate or 'Green Pass' will be mandatory to travel to European countries and the document will serve as proof that a person is vaccinated against Covid19.

External affairs minister S. Jaishankar on Tuesday took up the issue of inclusion of Covishield in the EU digital

Covid certificate scheme during a meeting with Josep Borrell Fontelles, the High Representative of the European Union. The meeting took place on the sidelines of a G20 meeting in Italy. THE EUROPEAN Union Digital Covid Certificate framework, or the Green Pass, to facilitate free movement during the Covid pandemic, came into effect on July 1 under which persons vaccinated with vaccines authorised by the European Medicines Agency (EMA) will be exempt from travel restrictions within the EU.

A DAY AFTER INDIA flexed its muscle over discriminatory practice by the European Union with regard to Indian vaccines Covishield and Covaxin, nine EU countries gave their approval to the AstraZeneca vaccine for a 'green pass', allowing free travel in the region of those vaccinated with Covishield. They include Germany and Switzerland.

Source : Asian Age, 02.07.2021

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Expand the vaccine basket

The Centre must speed up negotiations with foreign companies towards the removal of stumbling blocks to expand coverage

The regulatory approval for the Moderna vaccine is a welcome development as it adds to the basket of Covid-19 vaccines and helps in expanding the coverage. This is crucial because of the growing concerns over the spread of the Delta Plus variant and the need to speed up inoculation drive to meet the target of covering the entire adult population by the year-end.

However, there is still no clarity on the issue of indemnity clause, whose removal the American pharma giant had asked for, nor are any details available regarding the number of doses to be imported from Moderna's India partner, Cipla. Nevertheless, it was significant that the Drugs Controller General had waived the bridge trials required of foreign vaccine manufacturers. This was one of their major demands and opens the possibility of reinforcing the country's vaccine basket. There is a need for greater transparency in the vaccination policy, a point highlighted by the Supreme Court. Without compromising on the safety norms, the Centre must speed up negotiations with the foreign companies towards the removal of other stumbling blocks in the introduction of the mRNA technology-based vaccines. Though an average of 60 lakh jabs were administered in the past 10 days, the pace is still not enough to meet the target set by the Centre. Moreover, most of the doses administered are the first shot of the two-dose regimen. India needs to administer a minimum of one crore doses a day to inoculate its 95-crore adult population by December.

Even five months after launching the vaccination drive, vaccine shortage remains an issue in many States. As a result, only 4% of India's population is fully vaccinated. In its affidavit submitted before the apex court, outlining the vaccination timeline, the Centre noted that the drive would gather further momentum after August with the projected acquisition of 135 crore doses. Indigenous manufacturers, Serum Institute of India (SII) and Bharat Biotech, will continue to be the mainstay of the endeavour with the latter's share estimated to go up three times. Both companies will need to ramp up production. If foreign vaccine makers like Pfizer and Johnson & Johnson and indigenous manufacturers like Biological E and Zydus Cadila can join in quickly, it would boost the country's efforts to overcome the pandemic. With experts warning that the coronavirus is here to stay, and new mutations are bound to occur in future, the need to diversify the vaccine baskets and develop boosters to tame the new strains of the pathogen has acquired a sense of urgency. Already, India has lost precious time as it was caught in a flawed vaccination policy marked by lopsided distribution and differential pricing.

Source : Editorial, Telangana Today, 02.07.2021

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Interest equalisation scheme for exporters extended by 3 months

The government has budgeted Rs 1,900 crore under the scheme for FY22, against Rs 1,600 crore (RE) for FY21. This scheme usually allows manufacturing and merchant exporters an interest subsidy of 3% on pre-and-post-shipment rupee credit for exports of 416 products (tariff lines).

The central bank's notification came after the government approved the extension of the scheme, with "same scope and coverage".

The Reserve Bank of India (RBI) on Thursday extended the validity of the interest equalisation scheme for pre-and-post-shipment rupee export credit by three months through September 30. This will continue to help exporters struggling to cope with the damage caused by the second Covid wave.

The government has budgeted Rs 1,900 crore under the scheme for FY22, against Rs 1,600 crore (RE) for FY21. This scheme usually allows manufacturing and merchant exporters an interest subsidy of 3% on pre-and-post-shipment rupee credit for exports of 416 products (tariff lines).

The central bank's notification came after the government approved the extension of the scheme, with "same scope and coverage". The move comes at a time when the country's exports have staged a rebound after witnessing a roller-coaster ride in the wake of the pandemic last fiscal.

Merchandise exports surged over 69% in May from a year before to $32.3 billion, driven by a favourable base and improved demand from key markets. Importantly, goods exports have now crossed the pre-Covid (same months in 2019) level for three straight months, in what appears to be a strengthening trade recovery.

Of course, export growth was low even before the pandemic — outbound shipments rose about 9% in 2018-19 but again shrank by 5% in 2019-20. So only a sustained uptick over the next 2-3 years would help recapture the lost heights.

Hailing the extension, A Sakthivel, president of the exporters' body FIEO, said the scheme will "help the identified export sectors to be internationally competitive and to achieve a higher level of export performance".

Source : Financial Express, 02.07.2021

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Anti-diabetic drug promises therapeutic solution to COVID-19 infection

An anti-diabetic drug 'Ertugliflozin', might provide a therapeutic solution to the COVID-19 infection as a repurposed drug. This is following 'in-vitro' and 'in-silico' studies done by the **ASPIRE-BioNEST**, a life sciences incubator jointly funded by Department of Biotechnology and University of Hyderabad (UoH), ReaGene Innovations and INDRAS private limited.

The findings announced here on Thursday indicate that this repurposed drug not only binds effectively to the receptor binding domain of the spike protein of COVID-19 further blocks binding to human ACE2 but also displays significant anti-inflammatory and antithrombotic properties in a 3D human vascular lung model, both of which are fundamentals in COVID-19 infection, said an official press release.

"This offers a safe, ready-to-use, cost-effective solution to humans who contract COVID-19 and immense potential to treat the infection. Our research proves its efficacy in the test-tube assays", said CEO of ReaGene Innovations Uday Saxena. This start-up is co-founded by Dr. Subramanyam Vangala, and Dr. Sreedhara Voleti, MD of INDRAS. Ertugliflozin is an FDA approved drug for type-2 diabetes, works as an inhibitor by removing excessive glucose through urine.

INDRAS focus is on consulting, contracting, and collaborative solutions to in-silico drug design, has prioritized about 8,000 FDA approved drugs to top-10 from their computational studies, which were further experimented by ReaGene Innovations for various in-vitro assays on cytokine storm, antithrombotic properties, and inflammatory marker reduction through various in vitro assays.

The path to find such a repurposed drug was critically planned and completed within a year of funding from the IT giant Tech Mahindra led by global practice head of life sciences Ratnakar Palakodeti and global head of makers lab Nikhil Malhotra, together with the scientific partnership of INDRAS and ReaGene.

The outcomes of the results of this research were recently published in a journal (BioRxIV) and a patent was filed. "We have found a molecule that can potentially attack corona virus. We have applied for a joint patent," said Mr. Malhotra. The results are highly encouraging, and further in animal models towards preclinical, and clinical outcomes in humans are yet to be conducted for this drug to be officially nominated as a therapeutic agent for COVID-19.

Source : V Geetanath, The Hindu, 02.07.2021

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J&J Says Its Vaccine Gives At Least 8-Month Immunity For Delta Variant

The shot neutralized the delta variant within 29 days of a first dose, and protection matured and improved over time, the company said.

Johnson & Johnson said that its single-shot coronavirus vaccine neutralizes the fast-spreading delta variant and provides durable protection against infection more broadly.

The company said in a statement Thursday that recipients of its vaccine produced strong neutralizing antibodies over the course of at least eight months against all variants including delta, which was first seen in India and has been spreading around the globe.

Delta is expected to become the dominant strain in the U.S. in the coming weeks, according to the Centers for Disease Control and Prevention. The J&J shot provides less protection initially than messenger RNA vaccines from Pfizer Inc. and Moderna Inc., and experts have been discussing whether some people may need booster shots to keep the virus at bay long-term.

"We're extremely happy, actually, and confident there's no need for the booster at the moment and we're protected against different strains," said Johan Van Hoof, J&J's global head of infectious diseases and vaccines, in an interview.

The shot neutralized the delta variant within 29 days of a first dose, and protection matured and improved over time, the company said.

With the latest data in hand, Van Hoof said J&J doesn't believe people who have been given its vaccine should need a booster within a year of having gotten it. "And if a boost is needed," he said, "we don't think we'll need to change the formulation."

Scientists and some vaccine manufacturers have been crafting updated versions of their shots to directly target the emerging variants, which have proved to be significantly more transmissible than the original virus that first emerged in Wuhan, China, in late 2019.

The continued evolution of the pathogen, however, is creating an ever-moving target, leading some to evaluate whether additional doses of existing immunizations may provide more protection.

The findings J&J disclosed Thursday were from two studies. The company evaluated the blood samples of eight participants in its late-stage clinical trial of the vaccine to assess neutralizing antibodies produced against the delta variant. Dan Barouch of Beth Israel Deaconess Medical Center evaluated the durability of the immune response in 20 participants of an early-stage vaccine study.

More robust results will be published in bioRxiv, an online research depository, the company said.

Two-Shot Regimen

Data released by the company showed antibody counts, known as titres, were substantially higher in response to the delta variant than the beta variant first detected in South Africa. J&J said a second dose of its vaccine is known to increase a person's antibody count. The company plans to report efficacy data from a late-stage trial of a two-shot regimen at the end of August, Van Hoof said.

The company is also studying its vaccine's ability to create T cells, another gauge of its protective power. The shot produced increasing T cell immunity against the virus and its variants over eight months, according to Van Hoof. J&J's shot has struggled to get broad traction amid production problems and after a brief pause in use as regulators investigated reports that some people suffered dangerous blood clots after receiving it. The pause was lifted after 10 days on April 23.

Source : Riley Griffin, Bloomberg, 02.07.2021

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New export strategy may focus more on key component

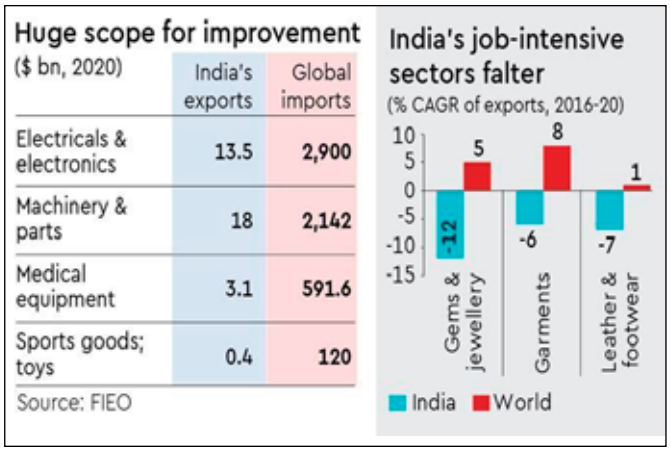
Mechanical machinery, electronics, medical and surgical equipment, sports goods, toys and certain farm commodities are among a number of products where India has the scope to substantially raise its exports, according to an analysis by exporters' body FIEO.

The allocation for RoDTEP may be raised by about Rs 4,000 crore, sources told FE.

Having set an ambitious goal to ship out merchandise worth $400 billion in FY22, India is firming up plans to bolster its exports of scores of key products where its share in the global market has traditionally remained paltry. Mechanical machinery, electronics, medical and surgical equipment, sports goods, toys and certain farm commodities are among a number of products where India has the scope to substantially raise its exports, according to an analysis by exporters' body FIEO.

For instance, in the electrical and electronics segments, India accounted for only 0.5% of the global supplies of $2,900 billion in the calendar year 2020. Similarly, while global imports of mechanical machinery and parts stood

at $2,142 billion in 2020, India's exports were just $18 billion, with a share of under 1%.



Of course, India's exports have risen at a faster pace than the global average in such capital and consumer goods in the last five years, it was aided by a low base. FIEO's analysis is part of its broader exercise to devise new strategy to improve exports.

Importantly, the rollout of production-linked incentive schemes for electronics products last year will help bolster our manufacturing base, which will ultimately help outbound shipments, FIEO reckons.

In medical & surgical equipment, against global imports of close to $592 billion in 2020, India's exports were only to the tune of $3.1 billion. In sports goods and toys, India's exports stood at just $380 million, against the global supplies of $120 billion in 2020.

As such, India's exports have trailed the global average in the last five years through 2020. While global imports grew at a compounded annual growth rate (CAGR) of 3% during 2016-2020, India's exports rose at only 2%. Of course, the outbreak of the pandemic and consequent lockdowns impacted India more adversely than most others in 2020.

However, what is a matter of concern is that exports from labour-intensive sectors are losing their share in the global market. In the gems & jewellery sector, global imports in the last five years through 2020 grew by CAGR of 5%, while India's exports contracted by a CAGR of 12%.

Similarly, while the woven garment imports worldwide remained static during 2016-2020, India's supplies shrank by a CAGR of 8%. In the leather footwear sector, in which global imports grew by a CAGR of 1% during 2016-2020, the country's exports contracted at a CAGR of 7%. However, in certain farm commodities, such as coffee, tea, spices, preparation of meat & fish, preparation of foods & vegetables, India's CAGR in exports has been more than the double that of global imports between 2016 and 2020. Here the country needs to build upon what it has achieved in recent years.

Source : FE Bureau, 03.07.2021

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Unjust green: On vaccine passports

India must continue to monitor discrimination in vaccine passports issue

The **European Union's decision to enforce a "Green Pass"** to allow travel within the EU from July 1, and linked to specified vaccines, has set off a storm of protest from several quarters including India. According to the European Medicines Agency (EMA) that sets the guidelines, the vaccines given "conditional marketing authorisation" were Comirnaty (Pfizer/BioNTech), Vaccine Janssen (Johnson & Johnson), Spikevax (Moderna) and Vaxzevria (AstraZeneca), which makes it clear that neither of India's vaccines, Covishield and Covaxin, as well as Russia's and China's, would be eligible for the EU Digital COVID Certificate (EUDCC), as the Green Pass is formally called. External Affairs Minister **S. Jaishankar took up the exclusion strongly with EU authorities** this week, particularly the case of Covishield, which is made under licensing and certification from AstraZeneca, and **cleared by WHO**. India has argued that the entire idea of "vaccine passports" would leave developing nations and the global south at a disadvantage, as they have restricted vaccine access. An unspoken but valid criticism is that there is a hint of racism in the action — the EMA list only includes vaccines already used by Europe and North America.

A letter of protest on the EMA's decision was also issued by the African Union and the Africa CDC this week, which called Covishield the "backbone" of the COVAX alliance's programme, that has been administered in many African countries. The EMA list is not binding however, and countries can choose to include others individually. After India's vocal protests, and its subtle threat to impose reciprocal measures, at least a third of the EU has said they would recognise Covishield (Estonia has accepted Covishield and Covaxin).

While the news that Austria, Estonia, Germany, Greece,

Iceland, Ireland, the Netherlands, Slovenia, Spain and Switzerland (not an EU member) have **accommodated India's concerns** is welcome, there are still some hurdles before Indian travellers. Most of these countries are not at present accepting Indian travellers at all, as no non-essential travel is allowed to EU countries, and the spread of the Delta variant, first identified in India, has meant further travel restrictions. In addition, Indians who have taken doses of Covaxin will need to wait even longer, until this vaccine receives WHO clearance. Finally, as more nations complete their vaccine programmes, they will seek to tighten their border controls with "vaccine passports" and longer quarantines in order to curtail the spread of new variants. While it is necessary for the Government to keep up with these actions worldwide, and battle discriminatory practices, the real imperative remains to vaccinate as many Indians as possible, given that more than six months after the Indian inoculation programme began, only 4.4% of those eligible have been fully vaccinated.

Source: Editorial, The Hindu, 03.07.2021

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Pharma PLI scheme to reduce India's dependence on API imports: Report

The agency opined that the scheme will benefit API manufacturers by giving them extra push to setup the necessary infrastructure along with their pre-planned infrastructure.

India's production-linked incentive (PLI) scheme will reduce India's dependence on imports for key active pharmaceutical ingredients (APIs) said India Ratings and Research (Ind-Ra). Accordingly, the rating agency expects import dependency to reduce around 43 per cent in the medium term from around 70 per cent currently.

"The scheme will not only attract foreign investments, but also promote the development of complex and high-tech products, emerging therapies and in-vitro diagnostic devices in India." "The benefits of the scheme will be a function of the pace of rollout of the scheme and interest of Indian pharmaceutical companies."

The agency opined that the scheme will benefit API manufacturers by giving them extra push to setup the necessary infrastructure along with their pre-planned infrastructure. "Whereas, the benefit to formulations manufacturers will be limited, because compared to the industry size, the incentives are unlikely to be strong enough for them to move up the value chain." "Bulk drug parks will help integrate infrastructure facilities, thereby reducing the manufacturing cost of APIs. Ind-Ra believes, if bulk drug parks are setup as envisaged to address infrastructure and approval issues, this will improve the ease of doing business."

The agency believes the PLI scheme to be a positive step in reducing India's dependence on China, though the benefits of the scheme will be visible after five to seven years. "Repeated raw material supply disruptions from China has been a cause of concern for global pharma companies including India, due to their high dependency on China." "MNC companies have started looking for an alternative to keep their supplies going uninterrupted." According to the government estimates, the scheme is expected to bring in investment of Rs 150 billion in the domestic pharmaceutical sector.

Source : IANS, 03.07.2021

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Skill development policy to be reviewed to match global standards

The government may revamp its umbrella framework for skilling in India, after undertaking a review of the National Policy for Skill Development and Entrepreneurship launched in 2015 with a focus on improving productivity to match global standards.

The plan is to create a pool of skilled workforce to cater to new investments being made under the government's production-linked incentive scheme for over a dozen sectors. The review due in 2020 was postponed in the wake of the pandemic.

The skills development ministry will set up a committee of experts to consider the evaluation study report of the 2015 policy to make necessary recommendations. Besides, a national-level institution with expertise on skilling will be appointed to undertake the impact assessment and recommend changes to the existing policy or the formulation of a new policy to ensure better outcomes over the next five years. A decision to this effect was made at the recently held second steering committee meeting of the National Skills Development Mission, a senior government official told ET. Prime Minister Narendra Modi had launched the initiative in July 2015 with an aim to make India the skills capital of the world.

The need for a complete overhaul of the policy is being felt as even after several years, standards of skilling as well as the rate continue to be low. This issue has been continuously flagged by industry, which faces a challenge in terms of skilled manpower.

The government has trained over 10 million youth in the last five years under its flagship scheme, the Pradhan Mantri Kaushal Vikas Yojana, which provides short-term training, skilling through ITIs and under the apprenticeship scheme.

The aim of the National Policy for Skill Development and Entrepreneurship 2015 was to meet the challenge of skilling in India at scale with speed, standard (quality) and sustainability. It was an umbrella framework for all skilling activities being carried out within the country so as to align them to common standards and link skilling with demand centres.

Source : Yogima Seth Sharma, ET Bureau, 05.07.2021

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All you need to know about Zydus' covid vaccine ZyCoV-D

Ahmadabad-based drugmaker Zydus Cadila has applied for an emergency-use authorization for its three-dose covid-19 vaccine ZyCoV-D. With a 'primary efficacy' of 66.6%, the jab, if approved, will be the world's first DNA vaccine. Mint explains:

What kind of vaccine is ZyCoV-D?

ZyCoV-D is a three-dose, plasmid DNA vaccine that produces the spike protein of the SARS-CoV-2 and elicits an immune response mediated by the cellular (T lymphocytes immunity) and humoral (antibody-mediated immunity) arms of the human immune system. It is also an intradermal vaccine, applied using a 'needle-free injector'. Zydus claims the needle-free system can lead to asignificant reduction in side effects.

The vaccine uses a 'plug and play' technology on which the plasmid DNA platform is based. It also means that a new form of the vaccine can be rapidly generated against any variant.

What is a plasmid DNA vaccine?

Plasmids are DNA molecules that replicate independently from the host'schromosomal DNA. Theyare mainlyfoundin bacteria. Aplasmid DNAvaccineinvolves injectinginto the appropriate tissues a plasmid containing the DNA sequence encoding of the antigen against which an immune response is sought, and relies on the in-situ (original) production of the target antigen. This approach offers a number of potential advantages over traditional approaches, including the stimulation of both B- and T-cell responses, improved vaccine stability,the absence ofany infectious agent and the relative ease of large-scale production.

What are the storage reqquirements for ZyCoV-D?

ZyCoV-D is stored at 2-8 degree Celsius, but it has shown good stability at temperatures of 25 degree Celsius for atleast three months. The company said the thermostability of the vaccine will help in easy transportation and storage and reduce any cold chain breakdown challenges. The vaccine is easy to manufacture with minimal biosafety requirements

What is ZyCoV-D's efficacy against covid?

Zydus claimed to have conducted the largest clinical trial for a covid-19 vaccine in India in over 50 centres. This was also the first time that any covid-19 vaccine had been tested in the 12-18-year age group in the country. Around 1,000 subjects were enrolled in this age group and the vaccine was found to be safe. The tolerability profile was similar to that seen in the adult population. Primary efficacy of 66.6% has been attained for symptomatic RT-PCR positive cases in an "interim analysis".

How many doses can Zydus produce?

Zydus Cadila has said it plans to manufacture 100-120 million doses of ZyCoV-D annually. Zydus will also be partnering with contract manufacturing organizations where it could potentially transfer its technology to produce another 50-70 million doses of the vaccine. The pharma company will be manufacturing the vaccine at its plant at the Zydus Biotech Park in Ahmedabad, Gujarat. It has invested 400-500 crore on clinical trials and scaling up manufacturing capacity.

Source : Neetu Chandra Sharma, HT Mint, 02.07.2021

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DRIVING UP THE DIGITALISATION GAME

TECHNOLOGY IS IMPACTING EVERY ASPECT OF OUR LIVES TODAY. FUTURE-ORIENTED COMPANIES MUST BECOME READY WITH THE NEXT LEVEL PHARMA TECHNOLOGIES, WHILE AIMING AT ENGAGING THE CONSUMER AT EVERY STEP

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Technology is is considered to be the driving force behind improvements in both healthcare and pharmaceuticals today. Thanks to technology, there is increased accessibility to treatment and medicines even in the midst of a pandemic-induced lockdown.

Against this backdrop, IndusNet Technologies, in association with *The Economic Times*, presented an episode of Digital Success dialogue where stalwarts from pharmaceutical and allied sectors deliberated on 'How digital transformation is driving the Indian Pharmaceutical sector towards global leadership'. Indian Drug Manufacturers' Association (IDMA) was the supporting partner. Panelists comprised Daara B Patel, secretary-general, IDMA; Dr Amit Rangnekar, chairman, Pricing Committee, IDMA; Salil S Kallianpur, founder & MD, ARKS Knowledge Consulting Pvt Ltd and Abhishek Rungta, founder and CEO, INT. It was moderated by Dinesh Chindarkar, co-founder and director, MediaMedic Communications.

Opening the session, Chindarkar's commented, "We are going through a complete disruption in healthcare. Similarly, a lot of acceleration has happened in the pharma industry as well. We are talking of augmented reality, virtual reality, predictive analytics - buzzwords within the industry." With this, he invited Patel to share his views on where see this going from here.

According to Patel, while the pharma industry started adopting technology some six years ago, it was never with the same gusto as we find now in the new normal. "During the lockdown, we have seen how digitalisation helps. Going forward, we will figure some hybrid way of working but digitalisation is certainly going to stay and be helpful," opined Patel.

Presenting an international perspective, Dr Rangnekar listed the four industrial revolutions in history and spoke specifically of Industry 4.0. that packs in Artificial Intelligence, Machine Learning, Big Data and Cloud Computing today. "We need to harness technology that is already there and based on that come out with a new product," he stated.

Kallianpur spoke of how the concept of time and distance has changed in new normal and people have got used to lack of physical proximity. "While a consumer gets service delivered at home, from a pharma marketing or service provider's point of view digital platforms create opportunities for them to gather a lot of data about customers. A lot of digitalisation is about personalisation," he felt.

With an outsider's approach to pharma, Rungta commented that tech change is also reflected in pharma industry. "Edge computing, which is decentralisation of computing, is visible in the health industry with different services being offered at home. Second thing I see in technology industry that will get reflected in pharma industry is micro service architecture where everybody is connecting to create an innovative product, and not working in isolation," he shared.

About Indian companies opening up to this digital transformation, Patel informed, "IDMA has gone virtual with all meetings and training programmes. To grow, you have to take the digital way. Not just the pharma industry, distributors too must become tech savvy," he replied.

About the disruption that is happening in the healthcare delivery, Kallianpur felt it is an extension of behaviour shift in consumers and the way service providers are reacting to it. "A hospital had a physical ecosystem of a diagnostic centre, pharmacy and I am trying to create the same ecosystem online. Healthcare at home has become important. Pharma companies must realise that their role is not just to make medicines but cure people," averred Kallianpur.

Dinesh directed Rungta to shed light on new technologies that pharma needs to adopt. "Pharma cos are coming up with insurance products. While physical companies struggle, digital ones control the consumer experience and the consumer. This is going to be critical. Secondly, health records on Blockchain, which is yet to reach Indian shores, will curb pilferages. Then there is this entire ecosystem in terms of biotech startups. Pharma companies must think of how to collaborate with these startups rather than compete with them," he enlightened.

Predictability in healthcare will make one participate in own healthcare decisions. Focus is shifting towards preventive management. About transforming traditional marketing, Kallianpur reiterated how data available through social listing and digital mapping are important tools that need to be added to traditional marketing armamentarium.

According to Rungta, one key learning that pharma can take is to keep an eye open to see what start-ups are doing. Phydigital is the way ahead. "Mass personalisation is the beauty of digital marketing. You must strike a balance to gain profit," added Patel.

Digitisation will proliferate every kind of activity. On that note, Dr Rangnekar said, "India is a fragmented market. Everyone will be connected digitally. We have to learn from each other." But Kallianpur put in that one must not do digital for the sake of it. Agreeing with him, Rungta concluded, "Look at digital as a tool to achieve a goal. Do not force fit it into the system."

We can assure quality through digitisation. There should be proper integration between IT and technically qualified pharma people

DAARA B PATEL
secretary-general, **IDMA**

We are going through a disruption in healthcare — integrated healthcare to healthcare at home services with healthcare startups booming and e-pharmacies going big

DINESH CHINDARKAR
co-founder and director
MediaMedic Communications

Data explosion is a challenge. You have to discern what is really important and give it to your customer. Digital gives you the opportunity to do so

DR AMIT RANGNEKAR
chairman, Pricing Committee, **IDMA**

A lot of digitalisation is about personalisation. If you make things relevant for the consumer you are approaching, engagement will definitely happen

SALIL S KALLIANPUR
founder & MD, **ARKS Knowledge Consulting Pvt Ltd**

Just like banks have been challenged by Fintechs, pharma will be challenged by biotech companies which will be coming to India soon

ABHISHEK RUNGTA
founder and CEO, **IndusNet Technologies**

Supporting Partner

Source : Irene Saha, Economic Times, 02.07.2021

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