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.

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.