Brief Guidance Document on Product Categories mentioned under PLI 2.0

1. Biopharmaceuticals

Biopharmaceuticals are drugs manufactured in, extracted from, or semi synthesized from biological sources e.g., Recombinant DNA derived therapeutic drugs, Vaccines, Biosimilars, Monoclonal antibodies.

2. Complex Generic Drugs

Complex generic drugs include complex active ingredients such as peptides, polymeric compounds; complex formulations such as liposomes; a complex route of delivery (e.g., locally acting drugs such as dermatological products and complex ophthalmological products and otic dosage forms that are formulated as suspensions, emulsions or gels); complex dosage forms such as Transdermal Patch; complex drug-device combination such as autoinjectors.

3. Patented drugs or drugs nearing patent expiry

Patented drug is any drug patented under any Patent Act having validity beyond 2028 and the drugs nearing patent expiry are the drugs that are going to be out of patent during 2021 to 2028 in the country of origin.

4. Cell based or gene therapy drugs

Cell based or gene therapy drugs include cellular therapy products include cellular immuno therapies; autologous and allogeneic cells for certain therapeutic indications, including hematopoetic stem cells; stem cells and stem cell derived products; human gene therapy products; cluster regularly interspaced short palindromic repeats (CRISPR) technology products.

5. Orphan Drugs

“Orphan Drug” means a drug intended to treat a condition which affects not more than five lakh persons in India. Orphan Drugs include drugs whose indication was approved by Central Drugs Standard Control Organization (CDSCO) for rare disease which are identified as rare diseases by the Indian Council of Medical Research (ICMR).

6. Special Empty Capsules like HPMC, Pullulan, enteric etc

Special Empty Capsules includes non-gelatin capsules such as HPMC, Pullulan, enteric etc.

7. Complex Excipients

Complex excipients are the excipients used in designing of complex formulations and any excipient that confers critical functionality to the dosage form such as pH dependent behavior, permeability enhancer, solubility enhancer.

8. Phyto-pharmaceuticals

Phyto-pharmaceutical drug is 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, but does not include drug administered through parenteral route.

9. Other drugs as approved (mentioned under sub-category 9 of Category 1 and subcategory 5 of Category 3 of scheme)

No product shall be considered under the aforesaid category unless the decision will be taken by the Department of Pharma to include any drug based on various factors/ circumstances.

10. Repurposed drug

Drug repurposing is defined as a process of identifying new therapeutic use for already approved drugs. It includes new indication as approved by the CDSCO, for domestic/ export; new indication as approved by other country regulator, for export only.

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