**File No. SND-16011(11)/94/2025-eoffice**
**Government of India**
**Directorate General of Health Services**
**Central Drugs Standard Control Organization**
**(Subsequent New Drugs Division)**

29 SEP 2025

**FDA Bhawan, Kotla Road**
**New Delhi-110002**

**Sub: Clarification for grant of permission for combipack product of lyophilised dry powder for injection/ I.V. infusion and diluents for reconstitution such as sterile water for injection /Sodium Chloride Injection -reg**

Representations has been received seeking clarification for regulatory pathway for the approval of Combi-pack product of Lyophilized dry powder for injection/ I.V. infusion and diluents for reconstitution such as Sterile water for injection /Sodium Chloride Injection.

The matter was examined and it is decided to follow the following pathway for grant of permission for Combi-pack products:

1. If the Lyophilized dry powder for injection/ I.V. infusion is approved by CDSCO for more than 04 years and it is being used with particular diluents as per prescribing information of said approved Lyophilized dry powder for injection/ I.V. infusion, then combi pack of such approved dry powder for injection/ I.V. infusion with same diluents is not considered as new drug and State Licensing Authority (SLA) may grant the permission.
2. Combi pack of approved dry powder for injection/ I.V. infusion with different diluents attracts the definition of New drugs as per Rule 2(1)(w) and permission from CDSCO is required as per the NDCT Rules 2019.
3. The drugs apart from (1) as mentioned above and which falls under definition of New Drugs as per NDCT Rules, 2019 require new drug permission from CDSCO before grant of license by SLA.

Accordingly, the applicants shall submit their application as mentioned above for grant of permission/License for Combi-pack products.

**(Dr. Rajeev Singh Raghuvanshi)**
**Drugs Controller General (India)**

**To,**

1. All State/UT Drugs Controllers.
2. CDSCO Zonal and Sub-Zonal offices.
3. All stakeholders through CDSCO website.