

Annexure-5

ADVISORY/GUIDANCE NOTE FOR PREVENTING SHORTAGE OF RABIES VACCINE, HUMAN & ANTI RABIES SERUM

1. Manufacturing of Rabies Vaccine, Human is a complex biological process and require a minimum of 3-4 months for manufacture and testing. Accordingly, the States/ procurement agencies may be sensitized about the minimum lead time required for supply, and plan.
2. Annual requirement of Rabies Vaccine, Human & Anti Rabies serum must be calculated 4-6 months in advance. Requirement must include 10% Wastage factor and buffer stock for three months (As lead time from order placement to actual delivery of vaccines). Accordingly, the tender/ purchase order needs to be placed in advance.
3. As per the Drugs and Cosmetics Rules, 1945, the batch of Rabies Vaccine, Human has to be released by the manufacturer after testing in manufacturer's laboratory and after ensuring that the vaccine complies with the specifications. It is also mandatory, as per procedures defined, to submit the samples of Rabies Vaccine, Human along with protocols to Central Drugs Laboratory (CDL), Kasauli for evaluation and lot release before it is supplied in the country. Normally, testing of Rabies vaccine, Human takes approximately 3 to 4 weeks.
4. Tenders should be issued for fixed quantities rather than the rate contracts.
5. Rabies Vaccine, Human & Anti Rabies serum stock must be monitored on regular basis. Monitor the district/ institute wise stock situation and accordingly, plan the supply based on consumption. If necessary, additional procurement order may be placed.
6. The States shall analyse average time required for completing tender process to actual placement of order and accordingly, the procurement procedures to be started well in advance to avoid shortage of Rabies Vaccine, Human & Anti Rabies serum supply.
7. The State Authorities need to be sensitized to analyse their annual requirement and the lead time required for completing all procedures well in advance, to guard against shortages in supply of Rabies Vaccine, Human & Anti Rabies serum.
8. Anti-rabies vaccine and Anti rabies serum is part of essential drug list of National Health Mission (NHM). Budget for Rabies Vaccine, Human & Anti Rabies serum may be proposed under NHM PIP under national free drug initiative.
9. As per national guidelines, the preferred route of administration for Rabies Vaccine, Human is Intradermal. It is cost effective and requires 0.2 ml/ Visit/patient for intradermal route vs. 1 ml/visit/patient for intra muscular route).
10. In case of shortage of Rabies vaccine, Human, please inform to National Pharmaceutical Pricing Authority (NPPA), Department of Pharmaceuticals (DoP) or Ministry of Health and Family Welfare (MoHFW) for addressing the issue. Non-supply of Rabies vaccine, Human due to pendency of bills should not be referred to DoP/MoHFW/CDSCO.