<u>CLARIFICATION regarding shelf life clause in Tender No.</u> <u>F.01(01)/RMSCL/PROCUREMENT/2012/01</u>

The required shelf life of 30 months in the tender is a general requirement. However, the shelf life can vary as per the nature of drugs. Certain drugs may have a shelf life lesser than that stipulated in tender conditions because of the inherent unstable nature. Many drugs have reduced shelf lives when formulated as liquids for oral or parenteral use. Following points are therefore clarified in this regard.

- (a) Shelf life of certain APIs (raw materials) specified in Schedule P is less than 30 months; in such cases, the shelf life of the formulations manufactured using such APIs may be 6 months less than the shelf life of its API, as specified in Schedule P.
- (b) The shelf life requirement for formulations of antibiotics, vitamins and steroids is reduced to 24 months from 30 months.
- (c) For other than above, the supplier may submit representation to RMSC & it will be examined on case to case basis for relaxation and decided on merit as per Drugs & Cosmetics Act and relevant rules.
- (d) For any deviation in the shelf life or supply period as stipulated, the supplier shall be responsible and shall be liable for any action against it in the form of non acceptance of goods or imposition of penalty or replacement of expired stocks with fresh stocks.