

No. 2018/H/4/1/DP/Policy

New Delhi, dated: 30.05.2019

Principal Chief Medical Directors,
All Indian Railways
&
Chief Medical Officers,
All Production Units including RDSO & NAIR.

Sub:- Registration of drug manufacturing firms and inspection of manufacturing units.

In terms of Drug Procurement Policy, a drug manufacturing/ marketing firm desirous of getting registered in the Railways, has to apply to the zones on laid down proforma duly enclosing the relevant documents as stipulated in the checklist. Thereafter, the zones are required to constitute a team for inspection of the Manufacturing Unit/office of the firm, as the case may be.

In the recent past, it has been observed from a few cases that though the firm had submitted request for inspection, such inspections are abnormally delayed and once the inspections have taken place, the proposals have been sent to Railway Board after more than a year's delay. In the mean time, the relevant documents of the firm have become outdated and back references have been sent to the zones for obtaining updated documents. **Such long delays taking place in Inspection of the Manufacturing Unit and submission of proposal to Railway Board has been viewed seriously and in a few cases zone(s) have been asked to fix individual responsibilities for such delays.**

In view of above, it has been **decided that the zones will ensure inspection of the Manufacturing Units/ Office, as the case may be, of the firm within a maximum period of two months from the date of receipt of the request in the zone.** Further, **after inspection of the Manufacturing Unit/Office of the firm, the proposal for approval of Competent Authority in Railway Board must be sent to this office within a maximum period of 10 working days thereafter.** Any delay in undertaking inspection/ sending proposal should be examined and responsibility on erring official(s) fixed before sending the proposal to Board.

For ensuring fair play, it has also been decided that henceforth, all the requests of the firm for inspection of Manufacturing Unit/ Office and other **documents must be got received in the zone under clear signature and stamp with date so that exact date of receipt of proposal in the zone is established.**

This has approval of Director General (RHS).


(R.S.Shukla/आर.एस. शुक्ल) 30/5/19

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