RPTUAS - Frequently Asked Questions (FAQs)

<u>Query 1</u>: (a) The current WHO-GMP certified pharmaceutical companies need upgradation due to age of facility and few upgradations in schedule M guidelines. Whether the PTUAS policy is extended to companies which are already WHO-GMP certified ?

(b) Is there any format of Gap analysis report to be submitted and any limit on the number of companies for this Gap analysis?

Reply :

(a) If the company is going from existing schedule M/ WHO-GMP to revised schedule M/ WHO-GMP, then there would be Gap Analysis and that Gap Analysis report is to be submitted to the PMA/SIDBI. Technical Committee/ CDSCO in the TC would take a call/ decision.

(b) For Gap analysis report format, there is an indicative form on application portal of SIDBI. The Gap Analysis format is attached at **Annexure.**

Query 2: Whether the scheme would be operational through SIDBI or any bank is also part of it ?

(b) It would be better if any bank is linked with this scheme

<u>Reply</u>: No particular bank is linked as of now. Earlier only scheduled commercial banks/ SIDBI (excluding cooperative banks) were linked to this scheme for loan purposes, but now this restriction has been done away with. This is a subsidy Scheme and there is no interest subvention. Further, there is no credit link and bank link to this scheme. Company can take loan from any bank and submit the application.

Query 3 : If any company has already started renovation work in December,2023 / January,2024, do these companies are eligible for incentive under this scheme ?

<u>Reply</u> : All investments made after 1St January, 2024 on eligible activities are eligible for getting incentive under the scheme.

Query 4: Who will be doing inspection of the project after Gap analysis report submitted by the company, as SIDBI don't have proper expertise / knowledge of the scheme ?

<u>Reply</u>: Generally, no specific inspection of the project is envisaged as CA certified expenditure statement is sufficient to assess expenditure made in the plant. Also, CDSCO officials know the details of location of plant which is mentioned in the CA report. Regarding fulfilling requirements of Revised Schedule M, assessment done by CDSCO officials will be considered as the definitive proof of attaining revised schedule M. Further, there is a Technical Committee constituted under the Scheme with experts from NIPER, CDSCO etc. to examine / offer technical guidance to the Department to process the proposals.

<u>Query 5</u>: Is there any cap on the investment to be made by the company under the scheme ?

<u>Reply</u> : There is no cap on the investment made by the company. However, there is a cap of Rs. 1 crore / plant on the incentive to be disbursed by DoP.

Query 6 : Is there any time frame to complete the upgradation work to be eligible for incentive under the scheme ?

<u>Reply</u> : Companies having average annual turnover of more than Rs. 250 crore need to submit the certification/ statement till June, 2024 for release of incentive. Companies with turnover below Rs.250 crore can submit the certification/ statement, till end of the year 2024 for release of incentive. (This is as per timelines stated in MoHFW notification on revised schedule-M dated 28/12/2023)

Query 7: One of the company has stated that it has submitted its application along-with all the requisite certificates in December, 2023 for WHO-GMP upgradation but still incentive has not been released by DoP. When will the expenditure be released to the company ?

<u>Reply</u>: After submission of the application by the company, the scheme has been revised/ revamped and revised schedule 'M' has come into force. Therefore, the application of the company would be considered and a decision will be taken to take it under new scheme or old scheme due to uniqueness of the case.

Query 8 : There are some schemes run by the State Govt. on technology upgradation of the plant as well. Are there any restrictions in availing both these similar schemes run by State Govt. as well as by DoP.

<u>Reply</u>: There is no restriction from DoP side to avail benefits from both the central/ State Scheme. But if there is some restriction regarding the same in the State Govt. scheme, then company has to disclose this while applying in DoP Scheme.
