

A Presentation
to
Pharma SSI Units, Andhra Pradesh
on
'Scheme for Schedule 'M' Compliance'
By
Dr.Ashok Vishandass, Dy.Director General
Department of Pharmaceuticals
Ministry of Chemicals & Fertilizers
Government of India
New Delhi
28th October, 2009

1

Prelude

- **The Department of Pharmaceuticals (DoP), GOI, New Delhi, in collaboration with M/O MSME introduced a Scheme for Schedule 'M' Compliance by SSI Units in Pharma Sector under the overall umbrella of the CLCSS.**
- **Effective from 13th July, 2009**

2

Prelude (Contd..)

- Second Supplement of the Revised Guidelines issued by MSME on the Credit Linked Capital Subsidy Scheme (CLCSS) for Technology Up-gradation
- The pharma SSI units will now be able to avail the benefits of CLCSS Scheme for financial assistance for an expanded list of products from 41 to 179.

3

Salient Features of the Scheme

- Arranging loan, upto Rs. 1.00 crore through public sector banks, for pharma SSI Units for schedule 'M' compliance
- Financial assistance in the form of Capital Subsidy @ 15% upto Rs.15 lakhs per Pharma SSI unit
- Technical advise & support for securing GMP certification from State Drug Controller
- Facilitating Capacity Building

4

Broad Objectives of the Scheme

- Technology upgradation by providing 15% upfront capital subsidy to pharma SSI units on institutional finances for inclusion of well established and improved technology in the pharma sector.
- Enable Pharma SSI Units to upgrade not only P&M but also manufacturing processes.
- To facilitate **quality** upgradation so that their **products command higher prices, higher turnovers & thus higher returns.**
- To facilitate pharma SSI units to secure **quality certification (GMP) for their units.**

5

Need of the Scheme

- Sizeable chunk of SSI pharma Units operates with outdated technology
- Low levels of productivity, higher costs, low turnovers & thus low returns;
- Unsustainable state of affairs; & hence the need to upgrade technology.

6

What the Scheme Offers

- ❖ The maximum limit of eligible loan under the scheme is Rs. 1.00 Crores.
- ❖ The ceiling on subsidy - Rs. 15 lakhs or 15% of the investment in eligible P&M, whichever is lower.
- ❖ The requirements of Schedule 'M' compliance include documentation - a very essential part. Pharma SSI units will be provided technical advice by NIPERs to secure the necessary certification from the concerned state Regulatory Authority.
- ❖ Industry graduating from small scale to medium scale on account of sanction of additional loan under CLCSS Scheme shall be eligible for assistance.

7

Why the Scheme?-Advantages

- **Manufacturing of quality medicines leads to higher returns through higher turnover.**
- Therefore, **it makes sense to manufacture quality medicines alone;**
- **Units availing assistance under the Scheme can also be given some motivational rewards in the shape of Standards, Productivity and Quality awards (SPQ Awards).**

8

Eligible Beneficiaries

The eligible beneficiaries include sole proprietorships, partnerships, co-operative societies, private and public limited companies in the pharma SSI sector.

9

Nodal Banks/Agencies for Implementation and Release of subsidy

S. No.	Nodal Bank/Agency
1	State Bank of India
2	Canara Bank
3	Bank of Baroda
4	Punjab National Bank
5	Bank of India
6	Andhra Bank
7	State Bank of Bikaner & Jaipur
8	Tamil Nadu Industrial Investment Corporation.
9	The National Small Industries Corporation Ltd.
10	Small Industries Development Bank of India (SIDBI)
11	National Bank for Agriculture and Rural Development (NABARD)

10

Coverage of Technologies under the Scheme

- ❖ **179 technologies / equipments / accessories under drugs & pharmaceuticals eligible for assistance under the scheme to meet the mandatory schedule 'M' requirements**
- ❖ **135 technologies pertain to formulations and remaining 44 for bulk drugs.**

11

Break-Up of 135 Machinery & Equipments for Formulations

S.N.	Type of Machinery /Equipment	No. of Machinery/ equip
1	External Preparations	8
2	Oral Liquid Preparations	9
3	Tablets	29
4	Capsules	6
5	Surgical Dressings	9
6	Ophthalmic Preparations	15
7	Peccaries & Suppositories	3
8	Inhalers & Vitrallae	3
9	Repacking of Pharma Chemicals	8
10	Parental Preparations	5
11	Container & Closer Preparations	6
12	Solutions Preparations	5
13	Filling Capping	10
14	Parental Preparations in Plastic Containers	5
15	Solution Preparation Area	14
	Sub-Total (Formulations)	135

12

Break-Up of 44 Machinery & Equipments for Bulk Drugs

S.N.	Type of Machinery /Equipment	No. of Machinery/ equip
1	Quality Control	5
2	Environment Control Devices	10
3	Others	29
	Sub-Total (Bulk Drugs)	44

13

Lead Players / Stakeholders

The scheme will involve collaboration with the following:

- Development Commissioner (MSME), Ministry of MSME
- Certification Agencies
- Banks and Financial Institutions like SIDBI
- State Government officials in Departments of Pharmaceuticals, Health and Industry

14

IMPLEMENTATION PROCESS

- **Technical and Certification Support:**
- As a number of Pharma SSI units are not well conversant with the technical requirements of the compliance regulators in terms of physical implementation processes, capacity building with the help of NIPER will be done.
- This will sensitize the SSI units of the implementation issues and increase their commitment to the project.

15

Project Approval Support

- Each unit would be required to prepare Detailed Project Plan (DPP) for application to the Bank for financial assistance including loan and subsidy.
- SIDBI would coordinate and monitor all the applications which seek assistance under the Scheme.
- There will be weekly monitoring of applications filed and sanctioned as well as disbursements of loan and adjustment of subsidy in the loan amount.

16

Duration of the Scheme

The Scheme would continue till the end of XI Five Year Plan i.e. upto March 31, 2012.

17

Application Form

Application form for assistance under Credit Linked Capital Subsidy Scheme for Technology Upgradation of the Small Scale Industries (CLCSS)
(To be submitted in triplicate, Photocopies may be used)

1. Name of the firm/company.....
2. Constitution (Proprietary concern, partnership firm, Pvt. Ltd. Co., Public Ltd. Co., Co-op. Societies)
3. Name(s) of Proprietor/partners/directors sole
4. Category of borrower (women entrepreneur, SC/ST, Physically handicapped, Ex-servicemen, etc.)
5. Registered Office Address
.....Pin.....
Phone No.....Fax.....
E-mail.....
6. Factory Address.....Pin.....
Phone.....Fax.....
E-mail.....
7. Location of factory – Backward or Non- backward area.....
8. Date of incorporation/commencement of production.....
9. Product (s)/ Sub-sector.....
10. Installed capacity
11. Past Performance (for last three years on the basis of audited balance sheets- in respect of existing units. In respect of new units projections for next three years may be given.)

18

Application Form (contd.)

		Financial year (Y -1)	Financial year (Y -2)	Financial year (Y -3)
I	Net block			
II	Current assets			
III	Current liabilities			
IV	Term loan			
V	Share Capital			
VI	Reserve & Surplus (less accumulated losses)			
VII	Net worth $-(V+VI)$			

19

Application Form (contd.)

		Financial year (Y -1)	Financial year (Y -2)	Financial year (Y -3)
I	Total Sales			
II	Gross Profit (Before interest & depreciation)			
III	Depreciation			
IV	Interest			
V	Operating Profit			
VI	Net Profit (after tax)			

20

Application Form (concluded)

12. Total cost of scheme (as approved by Bank/FI) (Rs. In lakh)

13. Total Sources of funding (as approved by Bank/FI) (Rs. In lakh)

Term loan.....

Add share capital.....

Internal accruals.....

Capital Subsidy.....

14. Time frame for completion of the project.....

15. Incremental benefits from implementation of the project (indicate in terms of capacity utilization, increased sales, exports, reduction in cost of production, increase in productivity, quality upgradation, attainment of pollution standards- give quantitative results.)

16. List of eligible plant and machinery along with their detailed specifications, rates, quantities and total value for which subsidy under CLCSS is claimed.

DECLARATION

I/we, hereby declare that the information given above and the statement and other papers enclosed are to the best of our knowledge and belief are true and correct.

Place:

Date:

Signature (s)

Name and designation

Seal of the company

21

The Department of
Pharmaceuticals

Thanks

All the Participants

22