



AUGUST – SEPTEMBER 2020

NEWS LETTER

**BULK DRUG MANUFACTURERS ASSOCIATION
(INDIA)**

**C-25, Industrial Estate, Sanathngar,
Hyderabad-500018**

BDMA National President's AGM Speech on 19th September, 2020

Good afternoon, President Emeritus, Patrons, Management Committee members, Executive Committee Members and members,

It is gratifying to address this meeting as the National President of BDMA for the third consecutive year and thank you all for your continued support in discharging our duties.-

It gives me great pleasure to welcome you all to the 28th Annual General Body Meeting of Bulk Drug Manufacturers Association of India. I would have very much liked to meet and address you in person, but as you know, we are holding this meeting over a virtual platform due Covid issues. I would like to thank you for sparing the time and hope you and your family members are remaining healthy and staying safe. Fiscal year 2020 started off as a promising year on all fronts,. We were on track in terms of various programs until January 2020, when the country began witnessing early signs of the pandemic. In effect FY20 ended abruptly, and was clear that the summer season as well as the rest of FY21 would be challenging periods as well. As I speak, the infection rate continues to rise in several parts of the country, but we are learning to live and work in the changed circumstances. The advent of a some lifesaving medicines provides welcome relief and there is hope that a vaccine will be available in the first quarter of next calendar year. I must salute the spirit of the Government authorities, healthcare workers, police, and the public in general, in fighting the pandemic.

As leaders of the industry, in these unprecedented times, we are looking at constructive ways and means of dealing with the situation, taking care of all our members , we have looked at ways and means to help the Government and help the member industries around us in the best manner.

We have partnered with the Government to fight the pandemic.. Over the years, our association has aptly demonstrated this ability by bringing out innovations in the area of expanding our capabilities of self-sufficiency in providing medicines at affordable rates. In the year gone by, I strongly believe that our representations to various departments of Centre and State will be accorded due importance.

We support the Government's aim and objective of quality healthcare for all the people, especially the needy. The Indian pharmaceutical industry has come a long way in the last few decades and now supplies quality, safe and affordable medicines to the people of India and all over the world. We are proud to announce that we are playing a significant part in protecting public health, not only in India but all over the world.

I have associated with BDMA for over two decades and have been entrusted with various responsibilities as secretary, General Secretary, Vice President, Sr. Vice President, President and so on.

I am happy to say that BDMA is associated with central and State Authorities and policy makers providing timely suggestions with respect to new policies and amendments of the existing once.

Realizing the present, India- China relations Indian government has initiated a lot of steps to reduce our dependence on imports and strengthening indigenous production. This is the right opportunity for India to increase domestic production of critical APIs & intermediates. Government should do the following on priority:

- To make India hub for affordable medicines I suggest encouraging development of life sciences/pharmaceutical cluster in the country where companies, academic institutions and R& D institutes converge and give rise to meaningful collaborations in drug discovery.
- Focusing and funding the specific training required for workers to be ready to work in the Pharmaceuticals and API sector and strengthen the skills.
- Invest in life sciences research and encourage development of private sector in this industry.
- For the pharma industry to grow in India, both in terms of value and volume needs to strengthen its commercial capabilities, realize its research and development within and outside the industry, build Public Private Partnership to drive access and shape the market.,

In the last three to four years we have seen that sourcing of key starting materials from china has been difficult and will be more difficult further. The primary reason is due to change in environmental laws in China which have forced suppliers in certain provinces to either reduce the production capacity or to shut down entirely. Supply problems from china again resurfaced during the CoVId-19 crises this year.

- We suggest and strongly recommend for Financial support by Government of India for Pharmaceutical Companies under different schemes,
- Clinical trial protocol should be simplified,
- Help to strengthen relationship between academic institutes and the industry.

We are happy to inform you that

- Our proposal for setting up of Advanced Analytical Testing Facility and Training Center at Jeedimetla has received in principle approval from Department of Pharmaceuticals, Government of India under assistance to pharmaceutical industry for common facility scheme.

- BDMA had engaged School of life sciences, Central University, Hyderabad to study on “Isolation and taxonomic cauterization of drug resistance bacteria from the effluent and soil samples collected from the drug manufacturing units located in Hyderabad”. This sponsored study was of great help in defending our industries as the results are found to be negative.
- In continuation of the studies BDMA engaged University of Hyderabad to study on ‘Chemical and genomic approaches to investigate possible link between development of antimicrobial resistance (AMR) and pharma industry effluents’. The results of the project will be announced soon.
- TSPCB is supporting BDMA to study for root cause of pollution of Hussain sagar lake and to investigate scientifically and identify the problem

The covid-19 pandemic has exposed the heavy dependency of Indian pharmaceuticals on external sources of raw materials, This has especially impacted our antibiotics production, as disruption in critical APIs.

At a time when self-reliance is the motto of our nation it is imperative that the Indian pharmaceutical industry strengthen its supply chain, we as an industry need to ensure that our value chains are independent of the volatility that surrounds us, by mitigating the risk of raw material supply.

For self-sufficiency in the field of pharmaceuticals:

- India needs to invest in development of novel drugs that can be patented, through setting up of R&D centers that focus on innovation and discovery of molecules.
- Maintain Competitiveness. Indian government has taken steps to boost the production of KSMs including APIs and drug intermediates through a proposed incentive package (PLI SCHEME), taking advantage of this we as an industry need to leverage our high quality low cost manufacturing capabilities to ensure that we continue to provide the world with affordable medicines.
- Leverage expertise: Newer technologies for drug delivery and formats to increase their efficacy should be brought in.

As the world looks towards a sustainable alternative for procuring its drugs, India can emerge as a viable pharmaceutical sourcing option. We can therefore expect a renewed demand for a workforce skilled in pharmaceuticals, and life sciences. Post the pandemic, the working scenario will also no longer be the same, and organizations as well as individuals who adapt to technology will be at an advantage.

Lastly, with all the new initiatives planned and support from the Government, India will be a major force globally in the API sector. I once again thank BDMA for giving me this opportunity and wish you all best of luck.

THANK YOU.

LIST OF BDMA COMMITTEE MEMBERS ELECTED FOR THE YRAR 2020-21 IN THE AGM HELD ON 19TH OF SEPTEMEBR 2020

SIN o	Name	Company Name (M/s)	DESIGNATION
1	SHRI V.V. KRISHNA REDDY	SRI KRISHNA PHARMACEUTICALS LTD	NATIONAL PRESIDENT BDMA
2	SHRI M. NARAYANA REDDY	VIRCHOW LABORATORIES LTD	PRESIDENT EMERITUS BDMA
3	SHRI.B.R.SIKRI	ABS MERCENTILE PVT LTD	VICE PRESIDENT NORTH ZONE, BDMA
4	SHRI NARESH K GUPTA	LUPIN LIMITED	VICE PRESIDENT WEST ZONE, BDMA
5	SHRI R.K. AGRAWAL	NAKODA CHEMICALS LTD	SR.VICE PRESIDENT,BDMA
6	SHRI. R. SRINIVASA RAJU	STANDARD PRODUCTS MFG.CO.,	GENERAL SECRETARY,BDMA
7	SHRI M. VIJAY KIRAN	COVALENT LABORATORIES PVT. LTD.	SECRETARY, BDMA
8	SHRI ANUP VEER	VEERCHEMIE AND AROMATICS PVT. LTD	TREASURER,BDMA
35	SHRI M. JAYANT TAGORE	SYNTHOKEM LABS. PVT. LTD.,	PATRON, BDMA
9	SHRI. K. NITYANANDA REDDY	AUROBINDO PHARMA LTD.,	PATRON, BDMA
10	Dr. V.V. SUBBA REDDY	SRI KRISHNA PHARMACEUTICALS LTD	PATRON, BDMA
11	Dr. B. PARTHASARADHI REDDY	HETERO DRUGS LTD	PATRON, BDMA
12	Dr N.VENKATA REDDY	VIRCHOW LABORATORIES LTD	PATRON, BDMA
13	SHRI VENKAT JASTI	SUVEN LIFE SCIENCES LTD	PATRON, BDMA
14	SHRI P.V.RANVEER	VEERCHEMIE AND AROMATICS PVT. LTD.,	EXECUTICE COMMITTEE MEMBER, BDMA
15	SHRI D. RAJKUMAR REDDY	COREY ORGANICS LTD.,	EXECUTICE COMMITTEE MEMBER, BDMA
16	SHRI ANUP AGARWAL	SREEPATHI LABS PVT. LTD.,	EXECUTICE COMMITTEE MEMBER, BDMA
17	SHRI. K. SUBBARAO	GLOCHEM INDUSTRIES LTD	EXECUTICE COMMITTEE MEMBER, BDMA
18	SHRI G.MANIKYA REDDY	S.M. LABS PVT.LTD	EXECUTICE COMMITTEE MEMBER, BDMA

19	SHRI.J.SANJEEVA REDDY	ALISTER PHARM CHEM PVT LTD	EXECUTICE COMMITTEE MEMBER, BDMA
20	SHRI.K.RAJA RAO	KEKULE PHARMA LTD	EXECUTICE COMMITTEE MEMBER, BDMA
21	SHRI P LAKSHMAN RAO	RASULA PHARMACEUTICALS & FINE CHEMICALS	EXECUTICE COMMITTEE MEMBER, BDMA
22	Dr. RAVI PENMETSA	GLAND PHARMA PVT.LTD	EXECUTICE COMMITTEE MEMBER, BDMA
23	SHRI.M.BALA SUBBA REDDY	VIRUPAKSHA LABORATORIES PVT LTD	EXECUTICE COMMITTEE MEMBER, BDMA
24	SHRI V.VASUDEV GOUD	BALAJI FORMULATIONS PVT.LTD	EXECUTICE COMMITTEE MEMBER, BDMA
25	DR.C.R.NAIDU, IPS (RETD)	SRIAM LABS PVT LTD.	EXECUTICE COMMITTEE MEMBER, BDMA
26	SHRI SRINIVAS ISOLA	SREEPATHI PHARMACEUTICAL LTD.,	EXECUTICE COMMITTEE MEMBER, BDMA
27	SHRI N.SRINIVASAN-DIRECTOR	PORUS LABORATORIES PVT LTD	EXECUTICE COMMITTEE MEMBER, BDMA
28	SHRI TBNV SUNDER RAO	VISHNU CHEMICALS LTD.,	EXECUTICE COMMITTEE MEMBER, BDMA
29	SHRI RAVI SEELAM SHETTY	KREATIVE ORGANICS PVT. LTD.,	EXECUTICE COMMITTEE MEMBER, BDMA
30	Dr. GIRIDHAR THOTA	SHODHANA LABORATORIES LTD	EXECUTICE COMMITTEE MEMBER, BDMA
31	SHRI CH. A. P. RAMESHWAR RAO	RAKSHIT DRUGS PVT LTD	EXECUTICE COMMITTEE MEMBER, BDMA
32	SHRI M.V. RAMA RAJU	VASUDHA PHARMA CHEM LTD	EXECUTICE COMMITTEE MEMBER, BDMA
33	SHRI. P. RAMESH KUMAR	GLAND CHEMICALS PVT. LTD.	EXECUTICE COMMITTEE MEMBER, BDMA
34	Dr.PV APPAJI	MEENAXY PHARMA PVT LTD	EXECUTICE COMMITTEE MEMBER, BDMA
36	Dr. S.SURESH BABU	ENAL DRUGS PVT LTD	EXECUTICE COMMITTEE MEMBER, BDMA
37	SHRI DINESH DUA	NECTAR LIFE SCIENCES LTD	EXECUTICE COMMITTEE MEMBER, BDMA
38	SHRI RAVI YERRA	RA CHEM PHARMA LTD	EXECUTICE COMMITTEE MEMBER, BDMA
39	SHRI K. VAMSHIDHAR REDDY	EMMENNAR PHARMA PVT LTD	EXECUTICE COMMITTEE MEMBER, BDMA
40	SHRI M.UDAY KUMAR REDDY	MSN LABORATORIES PVT LTD	EXECUTICE COMMITTEE MEMBER, BDMA
41	SHRI C.S. RATNA PRASAD	VALENS MOLECULES PVT LTD	EXECUTICE COMMITTEE MEMBER, BDMA
42	SHRI S.V.RAO	STYRAX PHARMA PVT LTD	EXECUTICE COMMITTEE MEMBER, BDMA

43	SHRI V.MADHUKAR REDDY	S.M.LABS PVT LTD	EXECUTICE COMMITTEE MEMBER, BDMA
44	SHRI P.KIRAN KUMAR	Dr.REDDY'S LABS LTD	EXECUTICE COMMITTEE MEMBER, BDMA
45	SHRI P.MADANMOHAN REDDY	AUROBINDO PHARMA LTD.,	EXECUTICE COMMITTEE MEMBER, BDMA
46	SHRI RAHUL THOTA	SHODHANA LABORATORIES LTD	EXECUTICE COMMITTEE MEMBER, BDMA
47	SHRI LINGA REDDY SUNIL	SARACA LABORATORIES LTD	EXECUTICE COMMITTEE MEMBER, BDMA
48	SHRI NIKHIL THOTA	SHODHANA LABORATORIES LTD	EXECUTICE COMMITTEE MEMBER, BDMA
49	SHRI KARTHIK CHANDRA ISOLA	SREEAPTHI PHARMACEUTICALS LTD	EXECUTICE COMMITTEE MEMBER, BDMA
50	SHRI S.SREENATH	STYRAX PHARMA PVT LTD	EXECUTICE COMMITTEE MEMBER, BDMA
51	Dr Y.RAMACHANDRA REDDY	SRC LABORATORIES PVT LTD	EXECUTICE COMMITTEE MEMBER, BDMA

Pharma exports soar 15% in first half of FY21

The growth is driven by drug formulations and biologicals, shipment of which grew a record 21.85% year on year at \$8.99 billion in the April-September period as countries across the globe turned to India to meet a spike in demand amid the Covid-19 pandemic that caused lockdowns and production disruptions in many parts of the world.

Hyderabad: [Pharmaceuticals exports](#) from the country is on course to cross \$23b for the first time this fiscal after growing 14.85% yoy at \$11.78b in the first half, a senior [commerce](#) ministry official said.

“Going by the indications of demand for our [pharma](#) products across the globe, India is likely to maintain similar growth in pharmaceutical exports

during the second half of the fiscal as well to close the fiscal with exports of at least \$23b and may even touch \$24b,” said Ravi Uday Bhaskar, DG, [Pharmexcil](#).

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For the first time in the history of Indian pharmaceutical exports, formulations and biologicals accounted for 76.3% of the total pharma exports this first half, up from around 72% a year ago.

India had exported pharmaceuticals worth \$20.58 billion last fiscal.

“We had projected India to report \$22 billion of pharmaceutical exports last fiscal but we fell short and ended up at \$20.58 billion, owing to disruptions in logistics and lockdowns in various importing countries during Covid-19 pandemic in last quarter of fiscal ended March 2020,” Uday Bhaskar told ET.

Besides formulations and biologicals, herbal products also saw a record growth of 20.77% year on year in the first half at \$168.87 million. Herbal products account for less than 1.5% of Indian pharma exports.

Exports of bulk drugs, drug intermediates, Ayush, vaccines and surgicals declined marginally in the first half, owing to change in immediate healthcare focus of nations across the globe towards handling Covid-19 pandemic.

Bulk drugs and drug intermediates reported a fall of 4.5% at \$1.87 billion during this first half, down from \$1.96 billion last fiscal. “The fall in bulk drugs and drug intermediate exports can also be seen as a positive

development since most Indian companies have used them for value addition to make high-margin and high-value formulations, adding to the overall growth of Indian pharmaceutical exports,” Uday Bhaskar said.

Exports of vaccines dipped 7.27% in the first half at \$359.05 million while exports of surgicals and Ayush products remained almost flat, slipping 0.11% at \$317.07 million and by 0.65% at \$72.1 million, respectively.

“India exports vaccines mostly to meet the scheduled immunisation programmes to children by various countries and with the change in healthcare focus of these countries towards addressing Covid-19 pandemic, India saw a fall in vaccine exports,” said Uday Bhaskar.

However, the country “may see a significant surge in export of vaccines this fiscal if it succeeds in introducing Covid-19 vaccine before the fiscal end”, he added.

**MINISTRY OF CHEMICALS AND FERTILIZERS (Department
Of Pharmaceuticals) NOTIFICATION New Delhi, the 21st July,
2020**

**Subject:- Production Linked Incentive (PLI) Scheme for promotion
of domestic manufacturing of critical Key Starting
Materials (KSMs)/ Drug Intermediates(DIs) and Active
Pharmaceutical Ingredients (APIs) In India.**

No. 31026/16/2020-Policy.—1. Background

1.1. Drugs play a major role in healthcare delivery in the country. Continuous supply of drugs is necessary to ensure delivery of affordable healthcare to the citizens. Any disruption in supply of drugs can have significant adverse impact on drug security of the country.

1.2. Indian pharmaceutical industry is the 3rd largest in the world by volume and 14th largest in terms of value. India contributes 3.5% of total drugs and medicines exported globally. However, despite these achievements, India is significantly dependent on import of some of the basic raw materials, viz., bulk drugs that are used to produce the finished dosage formulations. India imports bulk drugs largely for economic considerations. Bulk drugs accounted for 63% of the total pharmaceutical imports in the country during FY 2018-19.

1.3. A committee on drug security constituted by the Department of Pharmaceuticals collated the details of APIs imported in the country and identified 53 APIs for which the country is heavily dependent on imports. A list of such APIs is given in Annexure A.

1.4. Drug security of the country is dependent upon our ability to ensure un-interrupted supply of quality bulk drugs and also our capacity to upscale their manufacturing to meet emergency situations. Self-reliance in manufacturing of drugs is, therefore, highly desirable.

1.5. With a view to attain self-reliance and reduce import dependence in critical APIs, a scheme called “Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India” has been approved by the Government of India on 20th March, 2020.

2. Objective:

The scheme intends to boost domestic manufacturing of identified KSMs, Drug Intermediates and APIs by attracting large investments in the sector and thereby reduce India’s import dependence in critical APIs.

3. Scope:

Under the Scheme, financial incentives shall be given based on sales made by selected manufacturers for 41 products. These 41 products, which cover all the identified 53 APIs, are listed in Annexure B.

4. Quantum of Incentive:

Financial incentive under the scheme shall be provided on sales of 41 identified products for six (06) years at the rates given below:

4.1. For fermentation based products, incentive for FY 2023-24 to FY 2026-27 would be 20%, incentive for 2027-28 would be 15% and incentive for 2028-29 would be 5%.

4.2. For chemical synthesis based products, incentive for FY 2022-23 to FY 2027-28 would be 10%.

5. Target Segments:

Four Target Segments covering 41 products are listed in Annexure B.

6. Applicability:

The scheme is applicable only for greenfield projects.

7. Eligibility

7.1. Support under the scheme shall be provided only to manufacturers of critical KSMs/DIs and APIs registered in India.

7.2. Eligibility shall be subject to threshold investment in green field projects as given in Annexure C.

7.3. Eligibility under the scheme shall not affect eligibility under any other scheme and viceversa.

8. Tenure of the Scheme:

The tenure of the scheme is from FY 2020-21 to FY 2029-30.

9. Application Window:

The application window for receiving the applications shall be 120 days.

10. Base Year:

Financial Year 2019-20.

11. Financial Outlay:

Total financial outlay of the scheme is Rs. 6,940 crore.

12. Basis of Computation:

Assessment of threshold investment and sales of manufactured products shall be based on details furnished to the Departments/Ministries/Agencies and Statutory Auditor certificates.

13. Approval and Disbursement Process

13.1. Application under the Scheme can be made by any manufacturer registered in India.

13.2. An initial application, complete in all aspects, shall have to be submitted within the application window.

13.3. Eligible applications will be appraised and considered for selection.

13.4. Incentive shall be released to selected applicants, meeting the required thresholds and whose disbursement claims are found to be in order.

8 THE GAZETTE OF INDIA : EXTRAORDINARY [PART I—SEC. 1]

14. Project Management Agency

14.1. The Scheme shall be implemented through a Nodal Agency.

14.2. Such Nodal Agency shall act as a Project Management Agency (PMA) and be responsible for providing secretarial, managerial and implementation support.

14.3. Detailed constitution, functioning and responsibilities of the PMA will be elaborated in the Scheme guidelines.

14.4. For carrying out activities related to the implementation of the Scheme, PMA would, inter alia, be responsible for

14.4.1. Appraisal of applications and verification of eligibility for support under the Scheme.

14.4.2. Examination of claims eligible for disbursement of incentive under the Scheme.

14.4.3. Compilation of data regarding progress and performance of the Scheme including threshold investment and sales of manufactured goods of applicants selected under the Scheme.

15. Empowered Committee (EC)

15.1. An Empowered Committee (EC) comprising of following members shall be formed under the Scheme:

CEO, NITI Aayog (Chairman)

Secretary, Department of Pharmaceuticals

Secretary, Department of Chemicals and Petrochemicals

Secretary, Department for Promotion of Industry & Internal Trade

Secretary, Department of Commerce Secretary, Ministry of Environment,
Forest and Climate Change

Secretary, Department of Health & Family Welfare

Experts may be invited as special invitees, as may be felt necessary,
from time to time.

15.2. The Empowered Committee will be assisted by a Technical Committee of experts constituted by Department of Pharmaceuticals.

15.3. The EC will consider applications, as found eligible by the PMA, for approval under the Scheme.

15.4. The EC will consider claims, as examined and recommended by the PMA, for disbursement as per the laid down procedure and guidelines.

15.5. The EC will conduct a periodic review of the projects of the selected applicants with respect to their investments, employment generation and production under the Scheme.

15.6. The EC will also be authorized to carry out any amendments in the Scheme and the guidelines except revising the incentive rates, ceilings or eligible products.

15.7. Detailed constitution, functioning and responsibilities of the EC will be elaborated in the Scheme guidelines.

16. The detailed guidelines of the scheme will be uploaded on the website of the Department.

17. This Notification supersedes the earlier Notification of Department of Pharmaceuticals issued on this subject vide Notification No 31026/16/2020-Policy dated 2nd June, 2020.

NAVDEEP RINWA, Jt. Secy.

9 Annexure A List of identified products

- | | |
|---------------------------------------|-------------------|
| 1. Amoxicillin | 9. Sulbactam |
| 2. Azithromycin | 10. Dexamethasone |
| 3. Erythromycin Stearate/
Estolate | 11. Prednisolone |
| 4. Ceftriaxone | 12. Metformin |
| 5. Cefoperazone | 13. Gabapentin |
| 6. Cefixime | 14. Rifampicin |
| 7. Cephalexin | 15. Vitamin B1 |
| 8. Piperacillin Tazobactam | 16. Vitamin B6 |

- | | | | |
|-----|-------------------|-----|---------------|
| 17. | Clindamycin | 48. | Oxcarbazepine |
| | Phosphate | 49. | Valsartan |
| 18. | Clindamycin | 50. | Olmesartan |
| 19. | Streptomycin | 51. | Atorvastatin |
| 20. | Neomycin | 52. | Acyclovir |
| 21. | Gentamycin | 53. | Lopinavir |
| 22. | Doxycycline | | |
| 23. | Potassium | | |
| | Clavulanate | | |
| 24. | Oxytetracycline | | |
| 25. | Tetracycline | | |
| 26. | Clarithromycin | | |
| 27. | Betamethasone | | |
| 28. | Ciprofloxacin | | |
| 29. | Losartan | | |
| 30. | Telmisartan | | |
| 31. | Artesunate | | |
| 32. | Norfloxacin | | |
| 33. | Ofloxacin | | |
| 34. | Metronidazole | | |
| 35. | Sulfadiazine | | |
| 36. | Levofloxacin | | |
| 37. | Meropenem | | |
| 38. | Paracetamol | | |
| 39. | Tinidazole | | |
| 40. | Ornidazole | | |
| 41. | Ritonavir | | |
| 42. | Diclofenac Sodium | | |
| 43. | Aspirin | | |
| 44. | Levetiracetam HCL | | |
| 45. | Carbidopa | | |
| 46. | Levodopa | | |
| 47. | Carbamazepine | | |

Annexure B

Target Segments I. Fermentation based KSMs/Drug Intermediates

1. Penicillin G
2. 7-ACA
3. Erythromycin Thiocynate (TIOC)
4. Clavulanic Acid

II. Fermentation based niche KSMs/Drug Intermediates/APIs

5. Neomycin
6. Gentamycin
7. Betamethasone
8. Dexamethasone
9. Prednisolone
10. Rifampicin
11. Vitamin B1
12. Clindamycin Base
13. Streptomycin
14. Tetracycline

III. Key Chemical Synthesis based KSMs/Drug Intermediates

15. 1,1 Cyclohexane Diacetic Acid (CDA)

16. 2-Methyl-5Nitro-Imidazole (2-MNI)

17. Dicyandiamide (DCDA)

18. Para amino phenol

IV. Other Chemical Synthesis based KSMs/Drug Intermediates/APIs

19. Meropenem

20. Atorvastatin

21. Olmesartan

22. Valsartan

23. Losartan

24. Levofloxacin

25. Sulfadiazine

26. Ciprofloxacin

27. Ofloxacin

28. Norfloxacin

29. Artesunate

30. Telmisartan

31. Aspirin

32. Diclofenac Sodium

33. Levetiracetam

34. Carbidopa

35. Ritonavir

36. Lopinavir

37. Acyclovir

38. Carbamazepine

39. Oxcarbazepine

40. Vitamin

B6 41. Levodopa

11

Annexure C

Eligibility Threshold Criteria

S. No.	Segment Threshold	Investment
1	Fermentation based 04 KSMs /Drug Intermediates	Rs. 400 crore
2	2 Fermentation based 10 niche KSMs / Drug Intermediates / APIs	Rs. 50 crore
3	Key Chemical Synthesis based	Rs. 50 crore
4	Other 23 Chemical Synthesis based KSMs / Drug Intermediates / APIs	Rs. 20 crore

Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates and Active Pharmaceutical Ingredients (APIs) In India and Scheme for Promotion of Bulk Drug Parks.

Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates and Active Pharmaceutical Ingredients (APIs) In India and Scheme for Promotion of Bulk Drug Parks.

NOTIFICATION New Delhi, the 21st July, 2020 Subject:- Scheme for Promotion of Bulk Drug Parks. No. 31026/16/2020-Policy.—

1. Background

1.1. Drugs play a vital role in healthcare delivery in the country. Continuous supply of drugs is necessary to ensure delivery of affordable healthcare to the citizens. Any disruption in supply of drugs can have significant adverse impact on drug security of the country.

1.2. Indian pharmaceutical industry is the 3rd largest in the world by volume and 14th largest in terms of value. India contributes 3.5% of total drugs and medicines exported globally. However, despite these achievements, India is significantly dependent on import of some of the basic raw materials, viz., bulk drugs that are used to produce the finished dosage formulations. India imports bulk drugs largely for economic considerations. Bulk drugs accounted for 63% of the total pharmaceutical imports in the country during 2018-19.

1.3. Future growth of pharmaceutical sector is contingent upon our ability to ensure uninterrupted supply of quality bulk drugs and our capacity to upscale their manufacturing during emergency situations. Self-reliance in manufacturing of bulk drugs is, therefore, highly desirable.

1.4. With a view to significantly bring down the manufacturing cost of bulk drugs and thereby increase the competitiveness of the domestic bulk drug industry by providing easy access to standard testing & infrastructure facilities, a scheme called “Promotion of Bulk Drug Parks” has been approved by the Government of India on 20th March 2020.

2. Objective

2.1. To promote setting up of bulk drug parks in the country for providing easy access to world class common infrastructure facilities to bulk drug units located in the parks in order to significantly bring down the manufacturing cost of bulk drugs and thereby make India self-reliant in bulk drugs by increasing the competitiveness of the domestic bulk drug

industry. 2.2. To help industry meet the standards of environment at a reduced cost through innovative methods of common waste management system.

2.3. To exploit the benefits arising due to optimization of resources and economies of scale.

3. Scope: Financial assistance under the Scheme will be provided for creation of common infrastructure facilities in three Bulk Drug Parks proposed by State Governments and selected under the scheme.

4. Financial Assistance: Financial assistance to a selected Bulk Drug Park would be 70% of the project cost of common infrastructure facilities. In case of North Eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh) financial assistance would be 90% of the project cost. Maximum assistance under the scheme for one Bulk Drug Park would be limited to Rs. 1000 crore.

5. Common Infrastructure Facilities: The common facilities provided to individual bulk drug units in the Bulk Drug Park such as central effluent treatment plant, solvent recovery and distillation plant, steam generation and distribution system, common cooling system and distribution network, common logistics facilities, advance laboratory testing centre, emergency response centre, centre of excellence etc.

6. Financial outlay: The total financial outlay of the Scheme is Rs. 3,000 crore.

7. Tenure of the Scheme: The tenure of the Scheme is from FY 2020-2021 to FY 2024-2025.

8. State Implementing Agency

8.1. A Bulk Drug Park project selected under the Scheme will be implemented by a State Implementing Agency (SIA).

8.2. SIA shall be a legal entity set up by the concerned State government for the purpose of implementing the Bulk Drug Park project.

9. Scheme Steering Committee

9.1. The proposals under the scheme will be approved by the Scheme Steering Committee (SSC) constituted by Department of Pharmaceuticals (DoP).

9.2. The composition of the SSC is as follows: Secretary, DoP - Chairperson Financial Adviser, DoP - Member Joint Secretary, Ministry of Environment, Forest and - Member Climate Change Joint Secretary, Department for Promotion of Industry - Member and Internal Trade Joint Secretary, Department of Health and Family Welfare - Member DCGI, Central Drugs Standard Control Organisation - Member Joint Secretary (Policy), DoP - Convenor The SSC may invite representatives of Industry Associations, R&D Institutions and other Government / Private sector expert organizations as special invitees as may be necessary from time to time.

9.3. The SSC shall take all decisions required for successful implementation of the scheme, including any modifications if required.

10. The detailed guidelines of the scheme will be uploaded on the website of the Department. 11. This Notification supersedes the earlier Notification of the Department of Pharmaceuticals issued on this subject vide no 31026/16/2020-Policy dated 2nd June, 2020.

NAVDEEP RINWA, Jt. Secy

No. G-30012/10/2020-Scheme
Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals

Shastri Bhawan, New Delhi

Dated 7th September, 2020

To

Shri V.V. Krishna Reddy
President
Bulk Drug Manufacturer's Association (India)
C-25, Industrial Estate
Sanathnagar, Hyderabad- 500018
Email: info@bdmai.org, reddyvvk@srikrishnapharma.com

Subject: Proposal from Bulk Drug Manufacturers Association (BDMA) to set up 'Advanced Analytical Testing Facility and Training Center' at Jeedimetla in Hyderabad under Assistance to Pharmaceuticals Industry for Common Facilities-reg.

Sir,

I am directed to refer to your letter no. nil dated 4.7.2020 on the subject mentioned above and to say that the Scheme Steering Committee (SSC) has given 'in-principle approval to set up 'Advanced Analytical Testing Facility and Training Center' at Jeedimetla in Hyderabad. This approval is valid for 6 month of issuance of this letter.

2. You are requested to provide the Detailed project Report (DPR) of the proposed project to this Department expeditiously for onward submission to Scheme Steering Committee (SSC) for seeking final approval of the project.

Yours faithfully



(N.K. Joshi)

Under Secretary to the Government of India

Tele No. 23383392

Email: navin.26@gov.in

Copy to

1. PSO to Secretary (Pharmaceuticals).
2. PPS to AS&FA
3. Steno to JS(NR).

Report on drop in pollution levels in and around Hyderabad as a result of lockdown for the last forty days

Reference: Tol article captioned “Do not let city’s green quotient dip post lockdown, urge experts” published in Sunday Times of India, Hyderabad on May 3, 2020.

This is in reference to the Times of India report referred above, we strongly put forward that the facts stated by the Tol are cent percent correct and there is tremendous improvement in air quality and water in the lakes. This information might have been also confirmed by the environment monitoring results of TSPCB. The increase in DO levels and reduction in BOD amply indicates the improvement. This is a big relief to the citizens and an indirect benefit of lockdown.

As reported many times earlier, the increase in pollution levels was mostly being attributed to industrial activity and in particular to the Bulk Drug and Pharma industries. We bring to your kind notice that during the lockdown period almost all the bulk drug units were operating as we were mandated to see that there is

no shortage of essential medicines in the country and also meet the export commitments being made by the government. Our industry was also exempted from the lockdown by the State Government in view of maintaining enough stocks of essential medicines.

It is submitted that in spite of drug manufacturing units being in operation the improvement in environment quality in Hyderabad indicates that adequate control and treatment systems are provided and no pollution caused by drug and pharma industry. The deteriorated environment quality during normal times could be due to vehicular pollution, discharge of untreated sewage into water bodies and unscientific collection and handling of solid wastes and in particular the Municipal Solid waste.

We also submit to you that based on earlier orders of **National Green Tribunal**, CPCB had conducted a detailed study of the industrial areas such as Bollaram, Bachupalli and Kazipalli some time back and reported that there is total compliance by the industries. It was also reported by CPCB that Patancheru and Jeedimetla CETPs are working efficiently and meeting all the discharge standards and there is no adverse impact on Musi river or STPs operated by HMWWSB.

Submitted for your information



TELANGANA STATE POLLUTION CONTROL BOARD

Paryavarana Bhavan, A-3, Industrial Estate, Sanathnagar, Hyderabad - 500 018.

Office : +91-40-2388 7500

Fax : +91-40-2381 5631

Grams : "Kalushya Nivaraana"

Lr.No.704/TSPCB/LAB/HC/2019 - 728

Date: 20.08.2020

To
Sri P.Eshwar Reddy,
Executive Director,
M/s.Bulk Drug Manufacturers Association,
674, Sanathnagar I.E.,
Hyderabad,
Telangana - 500 018

Sir,

Sub: TSPCB - Proposal of Study for Root Cause of pollution of Hussainsagar lake
by BDMA - Reg.

Ref: Bulk Drug Manufacturers Association mail dated: 1st July 2020

Kind attention is invited to the subject and reference cited.

It is to inform that Bulk Drug Manufacturers Association (INDIA) has requested TSPCB to join and also co-sponsor the study of pollution of Hussainsagar lake to investigate scientifically and identify the problem.

It is also to inform that the Board is monitoring Hussain Sagar lake every month regularly and furnishing the analysis data of Hussainsagar lake to various stake holder departments as and when required for taking necessary action.

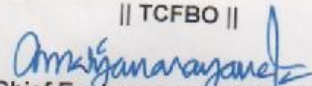
In this regard, it is to inform that the Board shall be part of the study by sharing the analysis data only and expertise if necessary. There shall be no financial commitment by the Board.

Yours faithfully,

Sd/-

MEMBER SECRETARY

|| TCFBO ||


Jt. Chief Environmental Scientist (FAC)