

Precedent Book -important decisions of Department of Pharmaceuticals

1. Important decisions of the Department:

- a. **Pharmaceuticals Promotion Development Scheme (PPDS):** Pharmaceuticals Promotion & Development Scheme (PPDS) launched in 2008 for promotion, development and export promotion in Pharmaceutical sector by extending financial support for conduct of seminars, conferences, exhibitions, mounting delegations to and from India for promotion of exports as well as investments, conducting studies/consultancies, for facilitating growth, exports as well as critical issues affecting Pharma sector.
- b. **Cluster Development Programme for Pharma Sector (CDP-PS):** With a vision to catalyze and encourage quality, productivity and innovation in pharmaceutical sector and to enable the Indian pharmaceutical industry especially SMEs to play a leading role in a competitive global market, Hon'ble Minister of Chemicals and Fertilizers approved the introduction of Cluster Development Programme for Pharma Sector (CDP-PS) on 27.10.2014.
- c. **Umbrella Scheme for promoting Pharma Industry:** The Department approved an Umbrella Scheme in May, 2018 namely 'Scheme for Development of Pharmaceutical industry'. The Umbrella Scheme now comprises of the following sub schemes including the earlier two schemes viz. CDP-PS and PPDS: -
 - (i) Assistance to Bulk Drug Industry for Common Facilitation Centres
 - (ii) Assistance to Medical Device Industry for Common Facilitation Centres
 - (iii) Assistance to Pharmaceutical Industry (CDP-PS)
 - (iv) Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS)
 - (v) Pharmaceutical Promotion and Development Scheme (PPDS).

In-principle approval of the Department of Expenditure has been received. This scheme was expected to help the industry to cut their cost of production resulting in making available quality medicines at reasonable prices.

- d. **Promotion of Medical Devices Parks:** The Union Cabinet in its meeting dated 20.03.2020 approved revision of the sub-scheme 'Assistance to Medical Device Industry for Common Facility Centre' to 'Promotion of Medical Devices Parks'. The total outlay of the scheme is Rs. 400 crore from FY 2020-21 to FY 2024-25. The guidelines of the scheme was issued on 27.07.2020.
- e. **Promotion of Bulk Drug Parks:** The Union Cabinet in its meeting dated 20.03.2020 approved revision of the sub-scheme "Assistance to Bulk Drug Industry for Common Facility Centre" to "Promotion of Bulk Drug Parks". The total outlay of the scheme is Rs. 3000 crore from FY 2020-21 to FY 2024-25. The guidelines of the scheme was issued on 27.07.2020.
- f. **Production Linked Incentive Scheme for promoting domestic manufacturing of medical devices:** The scheme with a total outlay of Rs. 3420 crore was approved by the Union Cabinet in its meeting dated 20.03.2020. The scheme proposes a financial incentive to attract large investments & boost domestic manufacturing. The incentive

of 5% will be provided to individual manufacturers based on their sale of medical devices from 04 identified target segments.

- g. **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:** The scheme with a total outlay of Rs. 6940 crore was approved by the Union Cabinet in its meeting dated 20.03.2020. Under the scheme, the financial incentive shall be provided for manufacturing of 41 eligible products for six years. For fermentation based eligible products, incentive for first four years (2023-2024 to 2026-2027) would be 20%, for fifth year (2027-28) incentive would be 15% and the sixth year (2028-2029) incentive would be 5%; on incremental sales of KSMs/Drug Intermediates/APIs. For chemically synthesis eligible products, incentive for six years (2022-2023 to 2027-2028) would be 10% on incremental sales of KSMs/Drug Intermediates/APIs.

2. Important Decisions related to PSUs

- a. **Union Cabinet in its meeting on 30.10.2013 approved Pharmaceuticals Purchase Policy (PPP) in respect of 103 medicines manufactured by pharma CPSEs and their subsidiaries.**
- b. **The Cabinet in its meeting dated 21.12.2016 approved the following: -**
- (i) Sale of surplus and vacant land of about 87.70 acres of HAL (actual area of land to be sold would depend upon the rates received in bids, as per guidelines of BIFR) to meet the net liabilities of Rs. 821.17 crore after waiver and deferment, through an open competitive bid from Central/State Government Departments, Government Agencies, Central/State PSU's, Autonomous Bodies, Urban Development Authorities, etc.
 - (ii) Waivers of Government of India loans and interest amounting to Rs. 307.23 crore. (Principal amount of Rs. 186.96 crore and interest approximately Rs. 120.27 crore thereon calculated as on 30.09.2017) and deferment of various dues amounting to Rs. 128.68 crores.
 - (iii) Sanction of an immediate loan of Rs. 100 crore to meet the wages, salaries and other critical expenses of immediate nature. The loan will be repaid to the Government from the sale proceeds of the HAL Land.
- c. **The Cabinet in its meeting dated 28.12.2016 approved the implementation of the recommendations of the Minister of Finance, Minister of Road Transport and Highways and Minister of Chemical and Fertilizers on future course of action on pharmaceutical companies in public sector as follows: -**
- (i) Only that much of surplus land of Hindustan Antibiotics Limited (HAL), Indian Drugs & Pharmaceuticals Limited (IDPL), Rajasthan Drugs & Pharmaceuticals (RDPL) and Bengal Chemicals & Pharmaceuticals Limited (BCPL) as would be required to meet the liabilities, be sold through open competitive bidding to Government agencies and the outstanding liabilities be cleared from the sale proceeds. Voluntary Separation Scheme/ Voluntary Retirement Scheme also be implemented in these PSUs to pave way for their closure. Remaining part of the land should be managed in accordance with guidelines of Department of Investment and Public Asset Management (DIPAM) and Department of Public Enterprises (DPE) in this regard and if need be, vested in a SPV created for this purpose.

(ii) After liabilities have been met, balance sheet cleansed and the Voluntary Separation Scheme/Voluntary Retirement Scheme effected, the IDPL & RDPL be closed and HAL & BCPL be put up for strategic sale.

(iii) While taking a decision to close the PSUs, the Department may also explore the possibility of hiving off the subsidiary companies of HAL and IDPL for private participation, wherever found viable.

- d. **CCEA on 01.11.2017 decided for Strategic Disinvestment of 100% GOI equity in KAPL.**
- e. **Cabinet approved on 20.11.2019 for extension/renewal of the extant Pharmaceuticals Purchase Policy (PPP) with the same terms and conditions while adding one additional product, namely, Alcoholic Hand Disinfectant (AHD) to the existing list of 103 medicines till the final closure/strategic disinvestment of the pharma CPSUs.**

3. Important decision related to National Pharmaceutical Pricing Authority (NPPA), an attached office of the Department:

- a. Notified norms for CCPC, PL and PM to non-PVC bag on port bag 500 ml under DPCO, 1995 on 10.09.2011.
- b. National Pharmaceuticals Pricing Policy for regulating pricing of Drugs to ensure availability, 7th December, 2012.
- c. Drugs Pricing Policy Order (DPCO-2013) notified in supersession of DPCO-1995 on 15.05.2013.
- d. NPPA approved the MRP under Para 19 of DPCO,2013 in respect of 106 Cardiac and Anti-diabetic non-scheduled formulations on 10.07.2014.
- e. Separate ceiling price for IV Fluid 100 ml/250ml/500ml and 1000ml having special features on 03.06.2016.
- f. Guidelines for Identification and Initiation of Overcharging cases issued on 07.10.2016.
- g. Ceiling Price Fixation for Coronary Stent (Gazette Notification No. SO 412(E) dated 13th February, 2017.
- h. Fixation of Ceiling Price of Cardiac Stents on 13.02.2017
- i. Ceiling Price Fixation for Orthopaedic Knee Implants (Gazette Notification No. SO 2668(E) dated 16th August, 2017.
- j. Fixation of Ceiling Price of Orthopaedic knee implants for knee replacement system on 16.08.2017.
- k. Revising in Ceiling Price of Cardiac Stents on 12.02.2018.
- l. Separate ceiling price for MDI and DPI containing Budesonide, Budesonide+ Formoterol and Tiotropium on 21.02.2019.
- m. Ceiling price fixed for orthopaedic knee implant was extended for a period of another one year on 13.08.2018. upto 15.08.2019.
- n. Capping of Trade Margin of 30% for non-scheduled 42 Anti-cancer drugs on 26.02.2019.
- o. Upward Price revision of 21 Scheduled formulation under Para 19 of DPCO, 2013 (One-time price increase of 50% from present ceiling price) on 09.12.2019.
- p. Incentivization for Incremental Innovation based on formula recommended by Multi-disciplinary Committee of Experts on 09.12.2019.
- q. Methodology for Price Fixation of off-patented medicines on 20.01.2020.
- r. Fixation of ceiling price based on Institutional Data on 25.02.2020.

- s. Separate ceiling price for ringer lactate injection 100 ml/250ml/500ml and 1000ml having special features on 03.03.2020.
- t. Monitoring of MRP of all Medical Devices notified as Drugs w.e.f. 01.04.2020 (Gazette Notification No. SO 1232(E) dated 31st March, 2020.
- u. Implementation of Eco-system for handling & Disposing the Application received at NPPA on 06.08.2020.
- v. Revision in guidelines for discontinuation of scheduled formulations on 14.08.2020.
- w. Fixing of Maximum Price for Liquid Medical Oxygen (LMO) and Oxygen Inhalation (Medicinal gas) in cylinder on 25.09.2020.

4. Important decisions related to National Institute of Pharmaceutical Education and Research (NIPERs):

- a. Establishment of six new NIPERs in 2007-08 at Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata and Raebareli with the help of Mentor Institutes
- b. Regularization of 151 (faculty and non-faculty) contractual employees of NIPER, Mohali vide Department's letter dated 17.03.2017.
- c. Evaluation of NIPERs by NITI Aayog in 2017.
- d. EFC meeting for construction and equipping of ten NIPERs held on 26/03/2018 recommended Rs.959.53 crore for construction/ equipping six NIPERs viz. Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata and Raebareli).
- e. Creation of 156 Faculty Posts and 150 non-Faculty posts in all NIPERs vide D/o Expenditure I.D.No.1009311/E.Coord.1/18 dated 17.01.2019.
- f. Extension of National Pension Scheme (NPS) to all NIPERs.
- g. Constituting the First Board of Governors (BoG) of all six NIPERs viz NIPER- Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata and Raebareli vide Department's order dated 09.03.2019.
- h. Constitution of Apex Council under the Chairmanship of Secretary (Pharma) vide this Department's order dated 07.05.2019.
- i. Implementation of 7th Central Pay Commission (CPC) for regular employees of NIPERs vide this Department's order dated 21.06.2019.
- j. Enhancement of fellowship of Junior Research Officers/Senior Research Officers of NIPERs from Rs. 25,000 to Rs. 31,000/Rs.28,000 to 35,000 vide Department's letter dated 30th July, 2019.
- k. Enhancement of payment of Honorariums to Member of Search/Selection/Assessment Committees/BoG of NIPERs vide this Department's letter no. 51020/1/2017-NIPER dated 27.09.2019.
- l. Enhancement of retirement age of all Faculty members and Directors of NIPERs from 60 to 65 years by laying of Notification published in the Gazette of India dated 27. 11.2019.
