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**STANDING COMMITTEE ON CHEMICALS &  
FERTILIZERS (2018-19)**

**SIXTEENTH LOK SABHA**

**MINISTRY OF CHEMICALS AND FERTILIZERS  
(DEPARTMENT OF PHARMACEUTICALS)**

*[Action Taken by the Government on the Observations / Recommendations contained in the Forty sixth Report of the Standing Committee on Chemicals and Fertilizers (Sixteenth Lok Sabha) on "Promotion and Co-ordination of Basic, Applied and other Research in areas related to the Pharmaceutical Sector" of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)]*



**FIFTY FIFTH REPORT**

**LOK SABHA SECRETARIAT  
NEW DELHI**

**FEBRUARY, 2019 /MAGHA, 1940 (SAKA)**

(i)  
FIFTY FIFTH REPORT

STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS  
(2018-19)

(SIXTEENTH LOK SABHA)

MINISTRY OF CHEMICALS AND FERTILIZERS  
(DEPARTMENT PHARMACEUTICALS)

*[Draft Action Taken Report on Action Taken Replies of the Government on the Observations / Recommendations contained in the Forty Sixth Report of the Standing Committee on Chemicals and Fertilizers (Sixteenth Lok Sabha) on "Promotion and Co-ordination of Basic, Applied and other Research in areas related to Pharmaceutical Sector" pertaining to Department of Pharmaceuticals]*

*Presented to Lok Sabha on 13 February, 2019*

*Laid in Rajya Sabha on 13 February, 2019*



LOK SABHA SECRETARIAT  
NEW DELHI  
FEBRUARY, 2019 /MAGHA, 1940 (SAKA)

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**COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS  
(2018-19)**

**Shri Anandrao Adsul - Chairperson**

**MEMBERS  
LOK SABHA**

2. Shri Sarfaraz Alam
3. George Baker
4. Shri B.N. Chandrappa
5. Shri Pankaj Chaudhary
6. Shri Sankar Prasad Datta
7. Dr. (Smt.) Ratna De (Nag)
8. Smt. Veena Devi
9. Shri R.Dhruvanarayana
10. Shri Innocent
11. Shri K. Ashok Kumar
12. Dr. (Prof.) Azmeera Seetaram Naik
13. Shri Chhedi Paswan
14. Smt. Kamla Devi Patle
15. Sushree Sadhvi Savitri Bai Phoole
16. Shri S. Rajendran
17. Dr. Kulamani Samal
18. Dr. Uma Saren
19. Dr. Krishna Pratap Singh
20. Smt. Rekha Arun Verma
21. Vacant

**RAJYA SABHA**

22. Shri Biswajit Daimary
23. Shri Prem Chand Gupta
24. Shri B.K. Hariprasad
25. Shri Ranvijay Singh Judev
26. Shri Sanjay Dattatraya Kakade
27. Elamaram Kareem
28. Dr. Sanjay Singh
29. Shri Vijay Pal Singh Tomar
30. Shri Abdul Wahab
31. Vacant

**SECRETARIAT**

1. Shri V.K. Tripathi - Joint Secretary
2. Shri C. Kalyanasundaram - Additional Director
3. Shri N. Amarathiagan - Under Secretary

## INTRODUCTION

I, the Chairperson, Standing Committee on Chemicals and Fertilizers (2018-19) having been authorized by the Committee to present the Report on their behalf, present this Fifty Fifth Report (Sixteenth Lok Sabha) on Action Taken by the Government on the observations/recommendations contained in the Forty Sixth Report (Sixteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers on "Promotion and Co-ordination of Basic, Applied and other Research in areas related to the Pharmaceutical Sector" of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

2. The Forty Sixth Report (Sixteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers was presented to Lok Sabha and laid in Rajya Sabha on **19.07.2018**. The Action Taken Replies of Government to all observations/recommendations contained in the Report were received on 14.01.2019. The Standing Committee on Chemicals and Fertilizers (2018-19) considered and adopted this Report at their sitting held on 11.02.2019.

3. An analysis of the Action Taken by the Government on the observations/recommendations contained in the Forty Sixth Report (Sixteenth Lok Sabha) of the Committee is given in **Appendix-II**.

4. For facility of reference and convenience, the Comments of the Committee have been printed in bold letters in the body of the Report.

New Delhi;  
11 February, 2019  
22 Magha 1940 (Saka)

ANANDRAO ADSUL  
Chairperson  
Standing Committee on  
Chemicals and Fertilizers

# REPORT

## CHAPTER-I

This Report of the Standing Committee on Chemicals and Fertilizers deals with the action taken by the Government on the Observations/Recommendations contained in the **Forty-Sixth Report** (16<sup>th</sup> Lok Sabha) of the Committee on the subject 'Promotion and co-ordination of basic, applied and other research in areas related to the Pharmaceuticals sector' was presented to Lok Sabha and Rajya Sabha on 19 July, 2018. In all, the Committee made 6 (six) Observations / Recommendations in the Report.

2. Ministry of Chemicals & Fertilizers (Department of Chemicals and Petrochemicals) were requested to furnish replies to the Observations / Recommendations contained in the Forty-Sixth Report within three months from the date of presentation of the Report, i.e. by 21 October, 2018. The Action Taken Replies of the Government in respect of all the six (06) Observations / Recommendations contained in the Report have been received from the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) vide their H-11011/05/2018-Parl. dated 14 January, 2019. These Replies have been categorized as follows:-

- (i) Observations / Recommendations that have been accepted by the Government :-

Sl. Nos. 1, 2 & 3 (Total =03)

These are included in Chapter II of the Report.

- (ii) Observations / Recommendations which the Committee do not desire to pursue in view of the Government's reply :-

Nil (Total = Nil)

- (iii) Observations / Recommendations in respect of which replies of the Government have not been accepted by the Committee :-

Sl. No. 5 (Total = 01)

This is included in Chapter IV of the Report.

- (iv) Observations / Recommendations in respect of which final replies of the Government are still awaited:-

Sl. No. 4 & 6 (Total=02)

These are included in Chapter V of the Report.

3. The Committee desire that the Action Taken Notes on the Observations / Recommendations contained in Chapter-I and V of this Report should be furnished expeditiously and not later than three months from the date of presentation of this Report.
4. The Committee will now deal with action taken by the Government on the Observations/Recommendations which still require reiteration or merit comments.

### **Recommendation (SI. No.1)**

#### **Post-WTO & TRIPS Challenges before Pharmaceutical research and development Indian Industry**

5. The Committee in their 46<sup>th</sup> Report (16<sup>th</sup> Lok Sabha) had observed / recommended as under:-

" India is globally considered the third largest producer of medicines by volume and the fourteenth in terms of value because of the fact that Indian medicines are among the lowest price in the world. India exports medicines to more than 200 countries and earns revenue more than Rs. 1,00,000 crore. Out of the total, production 50% medicines are consumed in the country itself and rest 50% are exported. This export of medicines is reckoned with third largest export sector in the country after gems & jewellery and textile sectors. The Committee note that this robust growth has taken place due to low cost manufacturing and skilled manpower. However, the Committee note that India had to make a paradigm shift in their pharmaceutical policy in the backdrop of post-WTO and TRIPS agreement in the mid-nineties. The country had to move from process patent regime to product patent regime by amending the Patent Act 1970 in 2005.

Under the TRIPS Agreement, WTO Members have to provide patent protection for any invention, whether a product or process for at least 20 years from the date on which the patent application was filed. This issue reiterated the urgency for India to have paradigm shift in its strategy to expand its leadership in Drug Discovery and Innovation. The Committee also note that the global pharmaceutical industry is shifting from chemical based medicines to biological based medicines.

The Committee note that the Department of pharmaceuticals in their pursuit to strengthen pharmaceutical invention and discovery, commissioned a Detailed Project Report for Developing India as a Drug Discovery and Pharmaceutical Innovation Hub presented by the firm - Ernst & Young, which highlights that India has emerged as a potent drug development service provider but not a key player in innovative product research. Indian bio-pharmaceutical companies are in early stage/biological research and translational research capabilities and R&D funding are weak compared to global bio-pharmaceutical companies. The Committee note that the contribution of Indian academia to new drug research is not substantive and as a result patents and publishing have not translated into licenses due to poor and inadequate alignment with private sector.

The Committee further note that pharmaceuticals sector in India is a multi-disciplinary and the research is spread across a large number of Ministries/Departments viz., Department of Biotechnology, Department of Science and Technology, Council for Scientific and Industrial Research, Indian Council for Medical Research, Department of Health and Family Welfare, Ministry of Human Resource Development, Ministry of AYUSH, and others.

In view of the aforesaid challenges both from internal and external environment, the Indian pharmaceutical Industry faces an uphill task to sustain their growth momentum in the backdrop of WTO and TRIPS regime. The Committee are of the considered view that to manufacture medicines at affordable prices for poor people in the country, it becomes quite imperative to revisit and explore the pharmaceutical regime by way of readjusting the existing policy and frame work of rules and regulation in the backdrop of requirements/commitments of WTO and TRIPS on priority to neutralize would be negative impact on the Indian Pharma industry. The Committee also desire that the action taken on the report submitted by the firm - Ernst & Young be expedited and the former be apprised of the steps taken in this regard."

### **Reply of the Government**

6. In reply to the aforementioned observations / recommendation of the Committee, the Department of Pharmaceuticals has stated as under :-

"The issues relating to WTO / TRIPS are being taken care by the Department of Industrial Policy and Promotion (DIPP). Under the TRIPS Agreement, WTO members have to provide patent protection for any innovation, whether a product or process for at least 20 years from the date on which the patent application was filed. The same has been guaranteed under Section 48 read with Section 53 of the Patents Act, 1970. TRIPS Agreement allows policy space to countries to evolve a regime that best suits its condition. India is a party to the Doha Declaration on the TRIPS Agreement and Public Health which clarifies that TRIPS agreement does not and should not prevent members from taking measures to protect public health. The Government of India has made several efforts so that patent legislation in India on the one hand utilizes the TRIPS flexibilities to ensure that access to healthcare does not suffer and on the other hand provides an IP framework conducive to protection of *bonafide* innovators. Subsequent to India becoming signatory to the TRIPS Agreement in 1995, Indian Patent laws were amended to comply with TRIPS. The Patents Act, 1970 was amended in 2005, whereby provisions were brought in for bringing pharmaceuticals or medicines under the product patent regime with effect from 1<sup>st</sup> January, 2005.

The recommendations in the Detailed Project Report for Developing India as a Drug Discovery and Pharmaceutical Innovation Hub presented by the firm, M/s Ernst & Young are under active consideration of the Department. NIPERs are having competent human resources, infrastructure and Academia Industry linkage. These



advantages put NIPERs ahead in working for new drug discovery. The Government is providing financial support for research and development through Drugs & Pharmaceuticals Research Programme (DPRP) run by the Department of Science & Technology. The companies undertaking Research & Development activities are provided income tax benefits. The Drugs (Prices Control) Order, 2013, Para-32(iii) provides exemptions from price control to a manufacturer producing a new drug involving a new delivery system developed through indigenous Research and Development for a period of five years from the date of its market approval in India.

In this connection, it may also be mentioned that Department of Pharmaceuticals has a Scheme namely Assistance to Pharmaceutical Industry with the objective to ensure drug security in the country by increasing the efficiency and competitiveness of domestic pharmaceutical industry."

### **Comments of the Committee**

**7. The Committee note that the Government is taking many steps in the post WTO / TRIPS regime towards ensuring drug security in the country by the way of promoting efficiency and competitiveness of domestic pharmaceutical industry. However, the Committee are perturbed over the fact that the challenges posed by the forces of open market mechanism in the post liberalization and post-WTO/TRIPS regime may prove to be an uphill task for the Indian Pharmaceutical Industry to retain their position and sustain the growth momentum. The Committee also take note that the Department of Pharmaceuticals is actively considering the recommendations made in the Detailed Project Report presented by the M/s Ernst & Young for developing India as a Drug Discovery and Innovation Hub. Innovation and new drug discoveries are need of the hour for the country. This Report should be studied by the Government in a time bound manner and necessary steps should be taken for world class research and development facilities in the country so as to make the country top most Drug Discovery and Innovation Hub in the world. In this regard, the Committee would like to be informed of the steps taken by the Government on the recommendations made in the Report of M/s Ernst & Young. The Committee also desire to be apprised of new initiatives, if any, being taken by the Department to promote Research and Development by the domestic pharmaceutical Industry to make them competitive both in the Indian and World Pharmaceutical Market.**

## **Recommendation (Sl. No.2)**

### **Need for Institutionalized Inter-Departmental Coordination Mechanism**

8. The Committee while emphasizing the need for setting up of an inter-departmental Coordination mechanism to coordinate research work in Pharmaceuticals sector had observed / recommended, in their 46<sup>th</sup> Report (16<sup>th</sup> Lok Sabha) as under:-

"The Committee note that to give boost to the pharma education and research, the Government created a separate Department i.e. Pharmaceuticals under the Ministry of Chemicals and Fertilizers in 2008 with the mandate to formulate pharma policy, planning, development and regulation of pharmaceuticals industries excluding those falling under the administrative control of other Ministries/Departments. The Department was also allocated to look after Inter-sectoral coordination including coordination between organizations and institutes under the Central and State Governments in areas related to the subjects entrusted to the Department. The Committee are unhappy to note that there has been no Inter-sectoral or inter-departmental coordination strong enough to put the mandate in proper perspective.

The Committee further note that pharmaceutical research is spread over a large number of Ministries/Department like Department of Biotechnology, Department of Science and Technology, Council for Scientific and Industrial Research, Indian Council for Medical Research, Department of Health and Family Welfare, Ministry of Human Resource Development, Ministry of AYUSH and others. This scattered pharmaceutical research involves lot of overlapping and duplication of research-projects ultimately leading to wastage of rare national resources allocated to different stakeholders. The Department also shared and endorsed the view of the Committee in this regard during their deposition before the Committee. The Department agreed with the proposal of the Committee for a separate inter-departmental Committee to be headed by the Secretary, Department of Pharmaceuticals to ensure no overlapping and duplication of efforts and resources and to conduct research in a collaborative, synchronized and synergized way for optimum utilization of funds allocated in this regard.

In view of the above, the Committee after having examined the subject in its entirety are of the strong view that there is an emergent need to institutionalized a robust mechanism of inter-departmental coordination in the Government to ensure economy, efficiency, effectiveness and transparency in the arena of Pharmaceutical research. The Committee further suggest that the budget allocation and any umbrella/National flagship scheme(s) to the pharma education and research be finalised by the Government only after consulting with this proposed inter-departmental mechanism.

The Committee also note that Ministry of Finance, Department of Expenditure vide their OM. No. 24(35)1PF-II/2012 dated 05.08.2015 had instructed for rationalisation of schemes which are to be implemented by various Ministries.

Subsequent to this instruction, the Department of Pharmaceuticals had proposed an umbrella Scheme for Development of Pharmaceuticals industry. While

expressing their satisfaction over such instruction of Ministry of Finance, the Committee are of the view that much is needed to be done to streamline and consolidate, the R&D activities by different organizations/institutions."

### **Reply of the Government**

9. In reply to the aforementioned observations / recommendation of the Committee, the Department of Pharmaceuticals has stated as under :-

"Department of Pharmaceutical has constituted an Inter-Departmental Committee (IDC) to coordinate research work in the area of Pharmaceuticals undertaken by organization and institutes under the Central Government vide Office Memorandum No. 31026/22/2018-Policy dated 09.01.2019.

Also, as per Ministry of Finance, Department of Expenditure's OM dated 05.08.2016, for rationalizing the schemes, the Department of Pharmaceuticals had prepared an umbrella scheme for "Development of Pharmaceutical Industry" with the objective to ensure drug security in the country by increasing the efficiency and competitiveness of domestic pharmaceutical industry with the following sub-schemes: (a) Assistance to Bulk Drug Industry for Common Facilities; (b) Assistance to Medical Device Industry for Common Facilities; (c) Pharmaceuticals Technology Up-gradation Assistance Scheme (PTUAS);(d) Assistance to Pharmaceutical Industry for Common Facilities and (e) Pharmaceutical Promotion Development Scheme (PPDS). The said scheme is a Central Sector Scheme with a total financial outlay of Rs. 480 cr.The scheme would help in cutting down cost of pharma production which would ultimately lead to reduction in the price of medicines. This would further ensure sustained availability of quality medicines at affordable prices to the patients"

### ***Comments of the Committee***

**10. The committee are happy to note that the Department of Pharmaceuticals has constituted an inter-Departmental Committee (IDC) to coordinate research work in the area of pharmaceutical undertaken by organizations/Institutes of Government of India. The Committee may be apprised of the role and responsibilities of the IDC and the steps taken for its efficient functioning. The Committee hope that the IDC mechanism will suitably address the issues and constraints affecting synchronization of various institutions involved in the process of innovation in pharmaceutical sector, bringing out new drugs and successful marketing of proven beneficial drugs. The Committee also feel that the Department of Pharmaceuticals and IDC can emulate the IMPRINT initiative of the Ministry Human Resources**

## **Development for the promotion of Research and Development and Innovation in the field of pharmaceuticals.**

### **Recommendation (Sl. No.3)**

#### **Linkage between Academia and Pharmaceuticals Industry**

11. The Committee, taking into account the lack of proper linkages between academic / research institutions and industry in the pharmaceutical sector of the country, had in their 46<sup>th</sup> Report (16<sup>th</sup> Lok Sabha), made the following recommendation :-

"The Committee note that a separate Department for pharmaceuticals was created in 2008 under the Ministry of Chemicals and Fertilizers with the mandate of policy, planning, development and regulation of pharmaceuticals industries excluding those specifically allotted to other departments. The subject - promotion and coordination of basic, applied and other research in areas related to the pharmaceutical sector was allocated to the newly created Department of Pharmaceuticals.

The Committee notice that the Department of pharmaceuticals set up 07 NIPERs under NIPER Act 1998 to boost pharma education and research other than the mandate of policy, planning, development and regulation of pharmaceuticals industries. The Committee have been apprised that these NIPERs have undertaken 21 Academia - Industry Linkage MOUs with leading pharma industries which include one each with 4 Pharma CPSEs i.e, Rajasthan Drugs and Pharmaceuticals Ltd (RDPL), Indian Drugs & Pharmaceuticals Limited (IDPL), Karnataka Antibiotics & Pharmaceuticals Limited (ICAPL) and Hindustan Anti-biotic Limited (HAL) and 2 with Bengal Chemicals and Pharmaceuticals Limited (BCPL) and 15 leading Private Pharma Companies in a bid to build Innovation Ecosystem in India. Other than this, NIPERs have signed MoUs with various PSUs and private pharmaceutical companies relating to collaborative research programmes in the areas of novel drug delivery, new drug discovery, pharmaceutical product development etc. along with the research activities, several knowledge-sharing sessions such as workshops and conferences.

The Committee were informed that a consortium of pharma industries for investing in R&D is a feasible option but the Government has already decided to either close or strategically sell all the pharma CPSUs. There is no specific mechanism to incentivize the pharma companies to undertake commercial production of new drug formulations discovered by various R&D institutions including NIPERs in the country. The Committee notice that however, the Department of Pharmaceuticals is in the process of facilitating the Pharma Industry to undertake commercial manufacture of bulk drugs including those based upon the discoveries technologies developed by R&D Institutions including NIPERs but the inadequate link between industry and academia has been a stumbling block in commercialization of the research work done in pharma academic institutes i.e. NIPERs.

The Committee strongly feel that there is an urgent need to convince the pharma industry about the efficacy, safety and effectiveness of research by way of reaching out to the pharma industry. Therefore, taking a holistic view of the subject, the Committee strongly recommend to create a common platform for exchange of ideas on present and future pharma research needs of country and the necessary mutual corporation between pharma industry and academia to jointly look at feasibility of converting research into commercial products."

### **Reply of the Government**

12. In reply to the aforementioned observations / recommendation of the Committee, the Department of Pharmaceuticals has stated as under :-

"As already indicated in reply to the Recommendation No. 2, the Department has recently constituted an Inter Departmental Committee to coordinate research work in the area of pharmaceuticals undertaken by organizations and institutes under the Central Government.

NIPERs, the autonomous education institutions under the aegis of the Department have signed various MoUs with industry for collaborations in the field of research and development. Further, the industry representatives are members on the Board of Governors (BoG) and other Committees of the institutes. The industry is also consulted, as appropriate, in framing/revision of the course curriculum.

A Technology Development Centre is functional at NIPER Mohali with liberal support of various industries. Training programmes and hands-on training on instruments for academic institutes and industries, and skill development programmes on GMP, have already been initiated at NIPER Mohali. Other NIPERs have also undertaken similar activities in collaboration with the industry, including public sector undertakings under the Department."

### ***Comments of the Committee***

13. **The Committee, taking into account the situation of inadequate link between industry and academia in commercialization of research work done by pharma institutions including NIPERs (National Institute of Pharmaceutical Education and Research), had inter-alia recommended to create a common platform for exchange of ideas between pharma R&D / academic institutions and the pharma industry of the country. In this regard, the Department of Pharmaceuticals has informed about the constitution of an Inter-Departmental Committee (IDC) to coordinate research works in the area of pharmaceuticals and also stated about collaboration between NIPERS and industry through MOUs, Training programmes, establishment of Technology Developments Centres at NIPERs, etc. The Committee while appreciating the positive aspects of the initiative taken by the Department, would like to highlight the need for**

creation of a common platform which can facilitate linkage between R&D institutions and the industry and exchange of ideas among the stake-holders that may pave the way for removal of bottlenecks in the process of drug-discovery, clinical trials by Central Drugs and Standard Control organization (CDSCO), approval/processing at Pharmacopeia Commission and production & marketing of new drugs by the industry, etc. The Department may also consider to institute annual awards both at national and at State/UT levels for domestic pharmaceutical companies which make outstanding contribution for the growth and development of Indian Pharmaceutical sector and for outstanding services provided to the society. Moreover, the Department may also like to explore the possibilities of bringing in much required synergy between NIPERs and one or more pharmaceutical PSUs as part of its efforts for creating the academic-industry linkage. The Committee may be informed of the action taken in this regard.

#### **Recommendation (Sl. No.5)**

#### **Need to enhance budget allocation for Pharma Research and Development**

14. On the need to enhance budget allocation for pharma research and development, the Committee in their 46<sup>th</sup> Report (16<sup>th</sup> Lok Sabha) had observed / recommended as under:-

"The Committee note that new Schemes for Assistance to Bulk drugs industry for Common Facilitation Centre, Assistance to Medical device Industry for Common Facilitation Centre, Cluster Development, Pharmaceuticals Technology Up-gradation Assistance Scheme (PTUAS) and Pharmaceuticals Promotion Development Scheme (PPDS) are proposed to be taken up for promoting the growth of Pharmaceutical and Medical Device Industry which came to fore after the instruction of Ministry of Finance on 5 August, 2018. But the Committee observe with dismay that no allocation for all these heads has actually been made by the Department of Pharmaceuticals. As such the Committee strongly recommend to allocate specific amount for all the schemes for the promotion of R&D as well as for the growth of Medical Device industry.

The Committee further noticed that there is no centralised mechanism to ensure no overlapping of research efforts takes place, which is prevailing at present. The Committee desire that pharmaceutical research be conducted in a synchronised and synergised way.

The Committee note that the expenditure incurred by NIPERs has been Rs. 400.02 crores under Grant-in-Aid-General provided for recurring expenditure like salary, stipend, office expenses etc. from 2012-13 to 2017-18. The Grant-in-Aid-

Capital has been Rs. 218.31 crores provided for creation of capital assets — construction of campus, purchase of equipment & machinery during the period 2012-13 to 2017-18. The Committee also note that Standing Committee on Finance (SFC) recommended a fund of Rs. 249.455 crores for NIPER Mohali alone during the 12th Five Year Plan period but they had received only Rs. 9.79 crores. The Department submitted the reason before the committee that till the Institutes do not submit their utilization certificate they cannot release new funds.

The Committee have noticed that one of the major challenges is that the Budget allocations made for Research and Development are thinly spread over many Ministries/departments/schemes and therefore the high capital needs of the pharmaceutical Research and Development are not adequately addressed to and as result, no tangible output is achieved. The Committee, therefore strongly recommend that there is need to develop innovation and research base of pharmaceuticals sector in India and for that robust budgetary support to Research and Development in pharmaceutical sector by making a separate head for Research and Development under budgetary allocation be made to Department of pharmaceuticals. "

### **Reply of the Government**

15. In reply to the aforementioned observations / recommendation of the Committee, the Department of Pharmaceuticals has stated as under :-

"Department has released Rs 7.38 cr.forresearch & development on TB and Kala Azarto NIPER Mohali. Besides, the Department has released Rs 14.00 cr. under GIA-Capital to NIPER Mohali for purchase of equipments during FY 2017-18. EFC in its meeting held on 26.3.2018 has approved Rs 100 cr. each for NIPER Ahmedabad, Guwahati and Hyderabad; and Rs 55.00 cr each for NIPER Hajipur, Kolkata and Raebareli for purchase of equipment and machinery during the period 2018-20."

### **Comments of the Committee**

16. **The Committee had strongly recommended for higher budgetary allocation for R&D and innovation and for the allocation of specific amount for new schemes which supports R&D, innovation and growth of pharmaceutical industry as well as Medical Device industry. The committee had also recommended for making a separate head for Pharmaceutical Research and Development in budgetary allocation to Department of Pharmaceuticals. However, the Action Taken Reply of the Government does not adequately addresses / explains recommendations made by the Committee. The Committee, therefore, would like to reiterate their previous recommendation. The Committee may be informed of the specific action taken towards promotion of R&D in pharmaceutical sector in terms of increased budgetary allocation / support / utilization. Further, the Committee may also be informed about the action taken on**

**the recommendation of the Committee for making a separate head for Research and Development under budgetary allocation to the Department of Pharmaceuticals.**

### **Recommendation (Sl. No.6)**

#### **Future Pharmaceutical Research**

17. With regard to future pharmaceutical research, the Committee in their 46<sup>th</sup> Report (16<sup>th</sup> Lok Sabha) had observed / recommended as under:-

"The Committee were apprised by the Department of Pharmaceuticals that Biologics also called Biopharmaceuticals have revolutionized vaccination programmes, treatment of chronic and serious illness like Rheumatoid arthritis, cancers, diabetes etc. and nudged traditional drugs out of top slots. Biologic drugs have been playing significant role in drugs have been playing significant role in meeting the unmet medical needs particularly in the field of non-communicable diseases including diabetes, auto-immune and various types of cancer disease etc.

The Committee are given to understand that a lot of deliberation has been made for the promotion and growth of R&D in Biologics, but still no headway has been made in the country. In India where people are badly affected by diabetes and cancer patients are increasing day by day with no much effective treatment, the Biologics is the need of hour. As such the Government should earmark a separate fund for the promotion and growth of Biologics. As submitted by the Secretary, Department of Pharmaceuticals, before the Committee that after five to seven years fifty percent medicines will be Biologics based, it is imperative that attention to R&D activities on Biologics be made in coordination with all the research organizations and industries. "

### **Reply of the Government**

18. In reply to the aforementioned observations / recommendation of the Committee, the Department of Pharmaceuticals has stated as under :-

"NIPER Mohali runs a M.S. (Pharm) course on Biotechnology and has a strong programme on affordable biopharmaceuticals and biologics. This includes components of downstream processing. The aim is to develop (i) cost-effective strategies for production of bio-generics making them affordable to the society, and (ii) novel drug candidates for the treatment of diseases with no known cure at present. The Institute has recently conducted an ITEC/SCAAP workshop on 'Recent Trends and Challenges in Biopharmaceuticals' (Oct. 30-31, 2018) which was attended by 23 participants from 12 countries and well appreciated by them.

The research facilities and skills for developing biologics and bio-similars require high end facilities with appropriate certifications. Setting up Centres for Excellence at each NIPER based on the respective expertise with a focused research area to promote basic and applied research areas in the area of Pharmaceutical Sciences is under consideration."



### ***Comments of the Committee***

19. The Committee had noted that Biologic drugs can play significant role in meeting the unmet medical needs particularly in the field of non-communicable diseases including diabetes, auto-immune and various types of cancer disease etc. Recognizing the significance of biologic drugs in future, the Committee had recommended to the Government to earmark a separate fund for the promotion and growth of Biologics. In this regard, the Department has *inter-alia* stated that setting up of Centers for Excellence at each NIPER based on the respective expertise with a focused research area to promote basic and applied research in the area of Pharmaceutical Sciences is under consideration. The Committee are also happy to note about the M.S. (Pharm) course on Biotechnology offered by NIPER Mohali and the recent workshop aimed at promoting Biopharmaceuticals and Biologics. The Committee would like to know further progress made in promotion and growth of Biologics. The Committee are also of the view that better results could be possible by bringing about synergy among NIPERs and research institutions under the Department of Biotechnology and the Ministry of AYUSH. The Committee may be apprised of the action taken in this regard. Further, the Committee again stress upon creation of a separate fund for the organized promotion and growth of Biologics which is a futuristic domain in pharmaceutical research.

## CHAPTER – II

### OBSERVATIONS / RECOMMENDATIONS WHICH HAVE BEEN ACCEPTED BY THE GOVERNMENT

#### Recommendation (Sl. No.1)

#### Post-WTO & TRIPS-Challenges before Pharmaceutical research and development Indian Industry

2.1 The observations / recommendations of the Committee are as under :-

" India is globally considered the third largest producer of medicines by volume and the fourteenth in terms of value because of the fact that Indian medicines are among the lowest price in the world. India exports medicines to more than 200 countries and earns revenue more than Rs. 1,00,000crore. Out of the total, production 50% medicines are consumed in the country itself and rest 50% are exported. This export of medicines is reckoned with third largest export sector in the country after gems & jewellery and textile sectors. The Committee note that this robust growth has taken place due to low cost manufacturing and skilled manpower. However, the Committee note that India had to make a paradigm shift in their pharmaceutical policy in the backdrop of post-WTO and TRIPS agreement in the mid-nineties. The country had to move from process patent regime to product patent regime by amending the Patent Act 1970 in 2005.

Under the TRIPS Agreement, WTO Members have to provide patent protection for any invention, whether a product or process for at least 20 years from the date on which the patent application was filed. This issue reiterated the urgency for India to have paradigm shift in its strategy to expand its leadership in Drug Discovery and Innovation. The Committee also note that the global pharmaceutical industry is shifting from chemical based medicines to biologics based medicines.

The Committee note that the Department of pharmaceuticals in their pursuit to strengthen pharmaceutical invention and discovery, commissioned a Detailed Project Report for Developing India as a Drug Discovery and Pharmaceutical Innovation Hub presented by the firm - Ernst & Young, which highlights that India has emerged as a potent drug development service provider but not a key player in innovative product research. Indian bio-pharmaceutical companies are in early stage/biological research and translational research capabilities and R&D funding are weak compared to global bio-pharmaceutical companies. The Committee note that the contribution of Indian academia to new drug research is not substantive and as a result patents and publishing have not translated into licenses due to poor and inadequate alignment with private sector.

The Committee further note that pharmaceuticals sector in India is a multi-disciplinary and the research is spread across a large number of Ministries/Departments viz., Department of Biotechnology, Department of Science and Technology, Council for Scientific and Industrial Research, Indian Council for Medical Research, Department of Health and Family Welfare, Ministry of Human Resource Development, Ministry of AYUSH, and others.

In view of the aforesaid challenges both from internal and external environment, the Indian pharmaceutical Industry faces an uphill task to sustain their growth momentum in the backdrop of WTO and TRIPS regime. The Committee are of the considered view that to manufacture medicines at affordable prices for poor people in the country, it becomes quite imperative to revisit and explore the pharmaceutical regime by way of readjusting the existing policy and frame work of rules and regulation in the backdrop of requirements/commitments of WTO and TRIPS on priority to neutralize would be negative impact on the Indian Pharma industry. The Committee also desire that the action taken on the report submitted by the firm - Ernst & Young be expedited and the former be apprised of the steps taken in this regard. "

### **Reply of the Government**

2.2 The Action Taken Reply of the Department of Pharmaceuticals is as under :-

"The issues relating to WTO TRIPTS are being taken care by the Department of Industrial Policy and Promotion (DIPP). Under the TRIPS Agreement, WTO members have to provide patent protection for any innovation, whether a product or process for at least 20 years from the date on which the patent application was filed. The same has been guaranteed under Section 48 read with Section 53 of the Patents Act, 1970. TRIPS Agreement allows policy space to countries to evolve a regime that best suits its condition. India is a party to the Doha Declaration on the TRIPS Agreement and Public Health which clarifies that TRIPS agreement does not and should not prevent members from taking measures to protect public health. The Government of India has made several efforts so that patent legislation in India on the one hand utilizes the TRIPS flexibilities to ensure that access to healthcare does not suffer and on the other hand provides an IP framework conducive to protection of *bonafide* innovators. Subsequent to India becoming signatory to the TRIPS Agreement in 1995, Indian Patent laws were amended to comply with TRIPS. The Patents Act, 1970 was amended in 2005, whereby provisions were brought in for bringing pharmaceuticals or medicines under the product patent regime with effect from 1<sup>st</sup> January, 2005.

The recommendations in the Detailed Project Report for Developing India as a Drug Discovery and Pharmaceutical Innovation Hub presented by the firm, M/s Ernst & Young are under active consideration of the Department. NIPERs are having competent human resources, infrastructure and Academia Industry linkage. These advantages put NIPERs ahead in working for new drug discovery. The Government is providing financial support for research and development through Drugs & Pharmaceuticals Research Programme (DPRP) run by the Department of Science & Technology. The companies undertaking Research & Development activities are provided income tax benefits. The Drugs (Prices Control) Order, 2013, Para-32(iii) provides exemptions from price control to a manufacturer producing a new drug involving a new delivery system developed through indigenous Research and Development for a period of five years from the date of its market approval in India.

In this connection, it may also be mentioned that Department of Pharmaceuticals has a Scheme namely Assistance to Pharmaceutical Industry with the objective to ensure drug security in the country by increasing the efficiency and competitiveness of domestic pharmaceutical industry."

[Ministry Chemicals & Fertilizers (Deptt. of Pharmaceuticals) OM No.H-11011/05/2018-Parl. dt. 14-01-2019]

### **Comments of the Committee**

(Please see Para No.7 of Chapter- I of the Report)

### **Recommendation SI. No.2**

#### **Need for Institutionalized Inter-Departmental Coordination Mechanism**

2.3 The observations / recommendations of the Committee are as under :-

"The Committee note that to give boost to the pharma education and research, the Government created a separate Department i.e. Pharmaceuticals under the Ministry of Chemicals and Fertilizers in 2008 with the mandate to formulate pharma policy, planning, development and regulation of pharmaceuticals industries excluding those falling under the administrative control of other Ministries/Departments. The Department was also allocated to look after Inter-sectoral coordination including coordination between organizations and institutes under the Central and State Governments in areas related to the subjects entrusted to the Department. The Committee are unhappy to note that there has been no Inter-sectoral or inter-departmental coordination strong enough to put the mandate in proper perspective.

The Committee further note that pharmaceutical research is spread over a large number of Ministries/Department like Department of Biotechnology, Department of Science and Technology, Council for Scientific and Industrial Research, Indian Council for Medical Research, Department of Health and Family Welfare, Ministry of Human Resource Development, Ministry of AYUSH and others. This scattered pharmaceutical research involves lot of overlapping and duplication of research-projects ultimately leading to wastage of rare national resources allocated to different stakeholders. The Department also shared and endorsed the view of the Committee in this regard during their deposition before the Committee. The Department agreed with the proposal of the Committee for a separate inter-departmental Committee to be headed by the Secretary, Department of Pharmaceuticals to ensure no overlapping and duplication of efforts and resources and to conduct research in a collaborative, synchronized and synergized way for optimum utilization of funds allocated in this regard.

In view of the above, the Committee after having examined the subject in its entirety are of the strong view that there is an emergent need to institutionalized a robust mechanism of inter-departmental coordination in the Government to ensure economy, efficiency, effectiveness and transparency in the arena of Pharmaceutical research. The Committee further suggest that the budget allocation and any umbrella/National flagship scheme(s) to the pharma education and research be

finalised by the Government only after consulting with this proposed inter-departmental mechanism.

The Committee also note that Ministry of Finance, Department of Expenditure vide their OM. No. 24(35)1PF-II/2012 dated 05.08.2015 had instructed for rationalization of schemes which are to be implemented by various Ministries.

Subsequent to this instruction, the Department of Pharmaceuticals had proposed an umbrella Scheme for Development of Pharmaceuticals industry. While expressing their satisfaction over such instruction of Ministry of Finance, the Committee are of the view that much is needed to be done to streamline and consolidate, the R&D activities by different organizations/institutions."

### **Reply of the Government**

2.4 The Action Taken Reply of the Department of Pharmaceuticals is as under :-

"Department of Pharmaceutical has constituted an Inter-Departmental Committee (IDC) to coordinate research work in the area of Pharmaceuticals undertaken by organization and institutes under the Central Government vide Office Memorandum No. 31026/22/2018-Policy dated 09.01.2019.

Also, as per Ministry of Finance, Department of Expenditure's OM dated 05.08.2016, for rationalizing the schemes, the Department of Pharmaceuticals had prepared an umbrella scheme for "Development of Pharmaceutical Industry" with the objective to ensure drug security in the country by increasing the efficiency and competitiveness of domestic pharmaceutical industry with the following sub-schemes: (a) Assistance to Bulk Drug Industry for Common Facilities; (b) Assistance to Medical Device Industry for Common Facilities; (c) Pharmaceuticals Technology Up-gradation Assistance Scheme (PTUAS);(d) Assistance to Pharmaceutical Industry for Common Facilities and (e) Pharmaceutical Promotion Development Scheme (PPDS). The said scheme is a Central Sector Scheme with a total financial outlay of Rs. 480 cr.The scheme would help in cutting down cost of pharma production which would ultimately lead to reduction in the price of medicines. This would further ensure sustained availability of quality medicines at affordable prices to the patients."

[Ministry Chemicals & Fertilizers (Deptt. of Pharmaceuticals) OM No.H-11011/05/2018-Parl. dt. 14-01-2019]

### **Comments of the Committee**

(Please see Para No.10 of Chapter- I of the Report)

## **Recommendation (Sl. No.3)**

### **Linkage between Academia and Pharmaceuticals Industry**

2.5 The observations / recommendations of the Committee are as under :-

"The Committee note that a separate Department for pharmaceuticals was created in 2008 under the Ministry of Chemicals and Fertilizers with the mandate of policy, planning, development and regulation of pharmaceuticals industries excluding those specifically allotted to other departments. The subject - promotion and coordination of basic, applied and other research in areas related to the pharmaceutical sector was allocated to the newly created Department of Pharmaceuticals.

The Committee notice that the Department of pharmaceuticals set up 07 NIPERs under NIPER Act 1998 to boost pharma education and research other than the mandate of policy, planning, development and regulation of pharmaceuticals industries. The Committee have been apprised that these NIPERs have undertaken 21 Academia - Industry Linkage MOUs with leading pharma industries which include one each with 4 Pharma CPSEs i.e, Rajasthan Drugs and Pharmaceuticals Ltd (RDPL), Indian Drugs & Pharmaceuticals Limited (IDPL), Karnataka Antibiotics & Pharmaceuticals Limited (ICAPL) and Hindustan Anti-biotic Limited (HAL) and 2 with Bengal Chemicals and Pharmaceuticals Limited (BCPL) and 15 leading Private Pharma Companies in a bid to build Innovation Ecosystem in India. Other than this, NIPERs have signed MoUs with various PSUs and private pharmaceutical companies relating to collaborative research programmes in the areas of novel drug delivery, new drug discovery, pharmaceutical product development etc. along with the research activities, several knowledge-sharing sessions such as workshops and conferences.

The Committee were informed that a consortium of pharma industries for investing in R&D is a feasible option but the Government has already decided to either close or strategically sell all the pharma CPSUs. There is no specific mechanism to incentivize the pharma companies to undertake commercial production of new drug formulations discovered by various R&D institutions including NIPERs in the country. The Committee notice that however, the Department of Pharmaceuticals is in the process of facilitating the Pharma Industry to undertake commercial manufacture of bulk drugs including those based upon the discoveries technologies developed by R&D Institutions including NIPERs but the inadequate link between industry and academia has been a stumbling block in commercialization of the research work done in pharma academic institutes i.e. NIPERs.

The Committee strongly feel that there is an urgent need to convince the pharma industry about the efficacy, safety and effectiveness of research by way of reaching out to the pharma industry. Therefore, taking a holistic view of the subject, the Committee strongly recommend to create a common platform for exchange of ideas on present and future pharma research needs of country and the necessary mutual corporation between pharma industry and academia to jointly look at feasibility of converting research into commercial products."

## **Reply of the Government**

2.6 The Action Taken Reply of the Department of Pharmaceuticals is as under :-

"As already indicated in reply to the Recommendation No. 2, the Department has recently constituted an Inter Departmental Committee to coordinate research work in the area of pharmaceuticals undertaken by organizations and institutes under the Central Government.

NIPERs, the autonomous education institutions under the aegis of the Department have signed various MoUs with industry for collaborations in the field of research and development. Further, the industry representatives are members on the Board of Governors (BoG) and other Committees of the institutes. The industry is also consulted, as appropriate, in framing/revision of the course curriculum.

A Technology Development Centre is functional at NIPER Mohali with liberal support of various industries. Training programmes and hands-on training on instruments for academic institutes and industries, and skill development programmes on GMP, have already been initiated at NIPER Mohali. Other NIPERs have also undertaken similar activities in collaboration with the industry, including public sector undertakings under the Department. .

[Ministry Chemicals & Fertilizers (Deptt. of Pharmaceuticals) OM No.H-11011/05/2018-Parl. dt. 14-01-2019]

### **Comments of the Committee**

(Please see Para No.13 of Chapter- I of the Report)

**CHAPTER – III**

**OBSERVATION / RECOMMENDATION WHICH THE COMMITTEE DO NOT DESIRE TO PURSUE IN VIEW OF THE GOVERNMENT'S REPLY**

**-NIL-**



## CHAPTER – IV

### OBSERVATIONS/RECOMMENDATIONS IN RESPECT OF WHICH REPLIES OF THE GOVERNMENT HAVE NOT BEEN ACCEPTED BY THE COMMITTEE AND WHICH REQUIRE REITERATION

#### Recommendation (Sl. No.5)

#### Need to enhance budget allocation for Pharma Research and Development

3.1 The observations / recommendations of the Committee are as under :-

"The Committee note that new Schemes for Assistance to Bulk drugs industry for Common Facilitation Centre, Assistance to Medical device Industry for Common Facilitation Centre, Cluster Development, Pharmaceuticals Technology Up-gradation Assistance Scheme (PTUAS) and Pharmaceuticals Promotion Development Scheme (PPDS) are proposed to be taken up for promoting the growth of Pharmaceutical and Medical Device Industry which came to fore after the instruction of Ministry of Finance on 5 August, 2018. But the Committee observe with dismay that no allocation for all these heads has actually been made by the Department of Pharmaceuticals. As such the Committee strongly recommend to allocate specific amount for all the schemes for the promotion of R&D as well as for the growth of Medical Device industry.

The Committee further noticed that there is no centralised mechanism to ensure no overlapping of research efforts takes place, which is prevailing at present. The Committee desire that pharmaceutical research be conducted in a synchronised and synergised way.

The Committee note that the expenditure incurred by NIPERs has been Rs. 400.02 crores under Grant-in-Aid-General provided for recurring expenditure like salary, stipend, office expenses etc. from 2012-13 to 2017-18. The Grant-in-Aid-Capital has been Rs. 218.31 crores provided for creation of capital assets — construction of campus, purchase of equipment & machinery during the period 2012-13 to 2017-18. The Committee also note that Standing Committee on Finance (SFC) recommended a fund of Rs. 249.455 crores for NIPER Mohali alone during the 12th Five Year Plan period but they had received only Rs. 9.79 crores. The Department submitted the reason before the committee that till the Institutes do not submit their utilization certificate they cannot release new funds.

The Committee have noticed that one of the major challenges is that the Budget allocations made for Research and Development are thinly spread over many Ministries/departments/schemes and therefore the high capital needs of the pharmaceutical Research and Development are not adequately addressed to and as result, no tangible output is achieved. The Committee, therefore strongly recommend that there is need to develop innovation and research base of pharmaceuticals sector in India and for that robust budgetary support to Research and Development in pharmaceutical sector by making a separate head for Research and Development under budgetary allocation be made to Department of pharmaceuticals. "

## **Reply of the Government**

3.2 The Action Taken Reply of the Department of Pharmaceuticals is as under :-

"Department has released Rs 7.38 cr. for research & development on TB and Kala Azarto NIPER Mohali. Besides, the Department has released Rs 14.00 cr. under GIA-Capital to NIPER Mohali for purchase of equipments during FY 2017-18. EFC in its meeting held on 26.3.2018 has approved Rs 100 cr. each for NIPER Ahmedabad, Guwahati and Hyderabad; and Rs 55.00 cr each for NIPER Hajipur, Kolkata and Raebareli for purchase of equipment and machinery during the period 2018-20."

[Ministry Chemicals & Fertilizers (Deptt. of Pharmaceuticals) OM No.H-11011/05/2018-Parl. dt. 14-01-2019]

## **Comments of the Committee**

(Please see Para No.16 of Chapter- I of the Report)

## CHAPTER – V

### OBSERVATIONS/RECOMMENDATIONS IN RESPECT OF WHICH REPLIES OF THE GOVERNMENT ARE STILL AWAITED

#### Recommendation (Sl. No.4)

#### Need to boost Infrastructure for Pharmaceutical Research and Development under NIPERs

4.1 The observations / recommendations of the Committee are as under :-

"The Committee note that the government has set up National Institutes of Pharmaceutical Education and Research (NIPERs) under NIPER Act 1998 as the higher premier institutions of education and research on Pharmaceuticals Sciences. Among these 7 functional NIPERs, at Mohali, Gandhinagar, Guwahati, Hajipur, Hyderabad, Kolkata and Rae Bareilly only one NIPER, Mohali is full-fledged with its own campus and sanctioned faculty, while all other 06 NIPERs are running from temporary accommodation/mentor institutions for the last 8 years. Apart from this, the Committee find that these NIPERs are run by contractual and adhoc faculty. Even at Mohali, the faculty is not at full sanctioned strength because of inadequate budgetary allocations.

Further, the Committee also note that in absence of Board of Governors, Steering Committee under chairmanship of Secretary, Department of Pharmaceuticals looks after administrative/financial matter of NIPERs on adhoc basis and the posts of Directors, NIPERs Hajipur and Hyderabad are still to be filled up. Lack of permanent campuses, well-equipped-laboratories, permanent faculty and staff and insufficient funding are some of the critical constraints which are considered a stumbling block to accomplish the academic and research agreed upon under MoUs with pharma industry.

The Committee were informed that a meeting of Expenditure Finance Commission (EFC) held under the chairmanship of Secretary, Expenditure, Ministry of Finance on 26.03.2018 has given its recommendations for providing infrastructure support, creation/filling up of posts etc. for existing NIPERs. Subsequent to the approval of the EFC action is being initiated for creation of academic and non-academic posts and appointment of regular faculty will rescue the attrition brain drain from these NIPERs.

The Committee having taken the requisite infrastructure like, building, state of the art labs and regular talented faculty into account as sacrosanct for pharmaceutical academics and research, strongly recommend to holistically address constraints concerning infrastructure, governance and human resource and make comprehensive strategy to boost pharmaceuticals research and development base of the existing NIPERs. The Committee also recommend the Department to pursue the cause of adequate budget with Ministry of Finance and to coordinate with the allied Ministries/Department like DBT/CSIR/ICNIR etc to get funds for NIPERs research projects.

Further, the Committee also suggest that Department to look into feasibility of creating two separate Departments i.e. academics and research with respective Head of Department under the Director of the Institute so that both the disciplines may be given due priority.

### **Reply of the Government**

4.2 The Action Taken Reply of the Department of Pharmaceuticals is as under :-

"In pursuance of the approval of EFC for construction, equipping and creation of posts in six NIPERs at a cost of Rs. 959.53 cr. during the period of 2018-20, follow up action are being taken by the Department. The progress has been reviewed at the level of Minister of State (Chemicals & Fertilizers). . The EFC has approved Rs. 103.88 cr. each for construction of campuses at Guwahati and Ahmedabad. Further, Rs. 100.00 cr. each for NIPERs at Ahmedabad, Guwahati and Hyderabad and Rs. 55.00 cr. each for NIPERs at Raebareilly, Hajipur and Kolkata have been approved for purchase of equipment and machinery at these institutes..

About 60% of the work of the construction of regular campus of NIPER Guwahati has been completed. The proposal for creation of posts is at advanced stage with the Ministry of Finance. The proposal for setting up of Board of Governors of the six NIPERs is at final stage. NIPERs, at the institutional level and their faculties at their level are seeking assistance from available schemes/ projects of the Departments concerned like DoNER, DBT, and DST etc.

The recommendation of the Committee to consider the feasibility of creating two separate departments - academic and research would be considered on creation and filling up of regular posts at NIPERs."

[Ministry Chemicals & Fertilizers (Deptt. of Pharmaceuticals) OM No.H-11011/05/2018-Parl. dt. 14-01-2019]

### **Recommendation (Sl. No.6)**

#### **Future Pharmaceutical Research**

4.3 The observations / recommendations of the Committee are as under :-

"The Committee were apprised by the Department of Pharmaceuticals that Biologics also called Biopharmaceuticals have revolutionized vaccination programmes, treatment of chronic and serious illness like Rheumatoid arthritis, cancers, diabetes etc. and nudged traditional drugs out of top slots. Biologic drugs have been playing significant role in drugs have been playing significant role in meeting the unmet medical needs particularly in the field of non-communicable diseases including diabetes, auto-immune and various types of cancer disease etc.

The Committee are given to understand that a lot of deliberation has been made for the promotion and growth of R&D in Biologics, but still no headway has been made in the country. In India where people are badly affected by diabetes and cancer patients are increasing day by day with no much effective treatment, the Biologics is the need of hour. As such the Government should earmark a separate

fund for the promotion and growth of Biologics. As submitted by the Secretary, Department of Pharmaceuticals, before the Committee that after five to seven years fifty percent medicines will be Biologics based, it is imperative that attention to R&D activities on Biologics be made in coordination with all the research organizations and industries. "

### **Reply of the Government**

4.4 The Action Taken Reply of the Department of Pharmaceuticals is as under :-

"NIPER Mohali runs a M.S. (Pharm) course on Biotechnology and has a strong programme on affordable biopharmaceuticals and biologics. This includes components of downstream processing. The aim is to develop (i) cost-effective strategies for production of bio-generics making them affordable to the society, and (ii) novel drug candidates for the treatment of diseases with no known cure at present. The Institute has recently conducted an ITEC/SCAAP workshop on 'Recent Trends and Challenges in Biopharmaceuticals' (Oct. 3013, 2018) which was attended by 23 participants from 12 countries and well appreciated by them.

The research facilities and skills for developing biologics and bio-similars require high end facilities with appropriate certifications. Setting up Centres for Excellence at each NIPER based on the respective expertise with a focused research area to promote basic and applied research areas in the area of Pharmaceutical Sciences is under consideration."

[Ministry Chemicals & Fertilizers (Deptt. of Pharmaceuticals) OM No.H-11011/05/2018-Parl. dt. 14-01-2019]

### **Comments of the Committee**

(Please see Para No.19 of Chapter- I of the Report)

**New Delhi;**  
**11 February, 2019**  
**22 Magha 1940 (Saka)**

**ANANDRAO ADSUL**  
**Chairperson**  
**Standing Committee on**  
**Chemicals and Fertilizers**

**MINUTES OF THE FIFTH SITTING OF THE  
STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2018-19)**

The Committee sat on Monday, the 11<sup>th</sup> February, 2019 from 1500 hrs. to 1545 in Room No.139, Parliament House Annexe, New Delhi.

**SHRI ANANDRAO ADSUL - CHAIRPERSON**

***MEMBERS***

**LOK SABHA**

2. Shri George Baker
3. Smt. Veena Devi
4. Shri R. Dhruvanarayana
5. Shri K. Ashok Kumar
6. Shri Chhedi Paswan
7. Smt. Kamla Devi Patle
8. Shri S. Rajendran
9. Dr. Kulamani Samal

**RAJYA SABHA**

10. Shri Elamaram Kareem
11. Shri Vijay Pal Singh Tomar

**SECRETARIAT**

- |    |                         |   |                     |
|----|-------------------------|---|---------------------|
| 1. | Shri V.K. Tripathi      | - | Joint Secretary     |
| 2. | Shri C. Kalyanasundaram | - | Additional Director |
| 3. | Shri N. Amarathiagan    | - | Under Secretary     |

2. At the outset, the Chairman welcomed the members of the Committee.

3. The Committee thereafter took up for consideration and adoption the draft Report on the subject 'Prices of Drugs with special reference to Drugs (Prices Control) Order, 2013' and draft Action Taken Report on 46th Report of the Committee on the subject "Promotion and Co-ordination of Basic Applied and other Research in areas related to the Pharmaceutical Sector" both pertaining to Department of Pharmaceuticals.

4. After deliberations, the Draft Reports were adopted by the Committee unanimously without any changes/amendments. The Committee authorised the Chairperson to finalize and present the Reports to the Parliament.

x.                   xxxxxx                   xxxxxx                   xxxxxx                   xxxxxx

The Committee then adjourned.

**Appendix – II**  
(Vide Para-3 of Introduction to Report)

**ANALYSIS OF ACTION TAKEN BY THE GOVERNMENT ON THE RECOMMENDATIONS CONTAINED IN THE FORTY-SIXTH REPORT (SIXTEENTH LOK SABHA) OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS ON THE SUBJECT 'PROMOTION AND CO-ORDINATION OF BASIC-APPLIED RESEARCH IN AREAS RELATED TO PHARMACEUTICAL SECTOR' OF THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACUETICALS)**

I	Total No. of Recommendations	6
II	Observations / Recommendations which have been accepted by the Government:  (Vide Recommendation Nos. 1,2 and 3 )	3
Percentage of Total		50.0%
III	Observations / Recommendations which the Committee do not desire to pursue in view of the Government's reply:-  NIL	0
Percentage of Total		0%
IV	Observations / Recommendations in respect of which reply of the Government have not been accepted by the Committee and which require reiteration:-  (Vide Recommendation No. 5 )	1
Percentage of Total		16.6%
V	Observations / Recommendations in respect of which final replies of the Government are still awaited:  (Vide Recommendation No.4 and 6)	2
Percentage of Total		33.3%