REPORT NO.
**110**

# PARLIAMENT OF INDIA
# RAJYA SABHA

## DEPARTMENT RELATED PARLIAMENTARY STANDING COMMITTEE ON COMMERCE

## ONE HUNDRED AND TENTH REPORT

## ON

## FDI IN PHARMACEUTICAL SECTOR

*(Presented to the Rajya Sabha on 13th August, 2013)*
*(Laid on the Table of Lok Sabha on 13th August, 2013)*

**Rajya Sabha Secretariat, New Delhi**
**August, 2013/Shravana, 1935 (Saka)**

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सत्यमेव जयते

**RAJYA SABHA SECRETARIAT**
**NEW DELHI**

AUGUST, 2013/ SHRAVANA, 1935 (SAKA)

**C O N T E N T S**

## COMPOSITION OF THE COMMITTEE

**(Constituted w.e.f. 31st August, 2010)**

1. Shri Shanta Kumar —*Chairman*

**RAJYA SABHA**

2. Prof. P. J. Kurien
3. Shri V. Hanumantha Rao
4. Dr. E.M. Sudarsana Natchiappan
5. Shri Arun Jaitley
6. Shri Jai Prakash
7. Shri K.N. Balagopal
8. Shri Ishwarlal Shankarlal Jain

# 9. Shri Prem Chand Gupta

@ 10. Shri Y. S. Chowdary

**LOK SABHA**

11. Shri G. S. Basavaraj
12. Shri Kalikesh N. Singh Deo
13. Shri K. P. Dhanapalan
14. Shri Shivarama Gouda
15. Shri Sk. Saidul Haque
16. Shri Dilip Singh Judev
17. Shri Nalin Kumar Kateel
18. Shri O. S. Manian
19. Shri Somendra Nath Mitra
20. Shri Deoraj Singh Patel
21. Shri Sanjay Dina Patil
22. Smt. Kamla Devi Patle
23. Shri Jagdish Singh Rana
24. Shri Gutha Sukender Reddy
25. Shri Modugula Venugopala Reddy
26. Shri Vishnu Deo Sai
27. Shri M. I. Shanavas
28. Shri Yashvir Singh
29. Shri Rajaiah Siricilla
30. Shri K. Sudhakaran
31. Shri Thol Thirumaavalavan

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# Nominated w.e.f. 17th September, 2009

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10. Shri Y. S. Chowdary

% Shri Rangasayee Ramakrishna

^ Shri Kiranmay Nanda

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16. Shri Shivarama Gouda
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20. Shri Nalin Kumar Kateel
21. Shri Dayanidhi Maran
22. Shri Vishnu Deo Sai
23. Shri M. I. Shanavas
24. Shri Jagdish Sharma
25. Shri Rajaiah Siricilla
26. Shri Dinubhai Boghabhai Solanki
27. Shri K. Sudhakaran
28. Shri Dharmendra Yadav

@ 29. Shri Modugula Venu Gopala Reddy

& 30. Shri K. Jayaprakash Hegde

31. Vacant

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@ Nominated w.e.f. 25th November, 2011
\# Retirement w.e.f. 2nd April, 2012
$ Retirement w.e.f. 2nd April, 2012
* Retirement w.e.f. 1st July, 2012
% Nominated w.e.f. 4th May, 2012
^ Nominated w.e.f 15th May, 2012
& Nominated w.e.f 18th May, 2012
** Re-nominated w.e.f 16th July, 2012.

## COMPOSITION OF THE COMMITTEE

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1. Shri Shanta Kumar —*Chairman*

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3. Shri Shadi Lal Batra
4. Shri P. Bhattacharya
5. Shri Rangasayee Ramakrishna
6. Shri K.N. Balagopal
7. Shri Ishwarlal Shankarlal Jain
8. Shri Prem Chand Gupta
9. Shri Birendra Prasad Baishya

$ 10. Dr. Vijay Mallya

**LOK SABHA**

11. Shri J.P. Agarwal
12. Shri G. S. Basavaraj
13. Shri Kuldeep Bishnoi
14. Shri C.M. Chang
15. Shri Jayant Chaudhary
16. Shri K. P. Dhanapalan
17. Shri Shivaram Gouda
18. Prof. Sk. Saidul Haque
19. Shri S.R. Jeyadurai
20. Shri Dilip Singh Judev
21. Smt. Putul Kumari
22. Shri P. Lingam
23. Shri Baijayant 'Jay' Panda
24. Shri Kadir Rana
25. Shri Vishnu Dev Sai
26. Shri Jagdish Sharma
27. Shri Adagooru Vishwanath
28. Shri Arun Yadav

\# 29. Shri Nalin Kumar Kateel

@ 30. Shri Nama Nageswara Rao

∗ 31. Shri Mukul Wasnik

**SECRETARIAT**

Smt. Sharada Subramaniam, Joint Secretary
Shri J. Sundriyal, Director
Shri Narendra Kumar, Deputy Director
Shri Amit Kumar, Assistant Director

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\# Nominated w.e.f. 14th December, 2012

@ Nominated w.e.f. 14th December, 2012

$ Nominated w.e.f. 26th February, 2013 vice Ms. Anu Aga who resigned from the membership of Committee on 20th December, 2012

∗ Nominated w.e.f. 1st May, 2013

## PREFACE

I, the Chairman of the Department Related Parliamentary Standing Committee on Commerce, having been authorized by the Committee, present this One Hundred and Tenth Report of the Committee on the subject 'FDI in Pharmaceutical Sector'.

2. The Committee took up the subject on 3rd May, 2011 and the same was issued *vide* Parliamentary Bulletin Part-II dated the 12th May, 2011. As part of examination of the subject, the Committee took series of evidences of stakeholders in both government and non-government sector. These included Secretaries and representatives of the Department of Industrial Policy and Promotion, Ministry of Commerce and Industry; Department of Health and Family Welfare, Ministry of Health and Family Welfare; Department of Economic Affairs, Ministry of Finance; Planning Commission; Department of Pharmaceuticals, Ministry of Chemicals and Fertilisers; Department of Scientific and Industrial Research; Competition Commission of India (CCI); National Pharmaceutical Pricing Authority (NPPA); Indian Pharmaceutical Alliance (IPA); Indian Medical Association (IMA); Federation of Medical and Sales Representatives' Association of India (FMRAI); Centre for Trade and Development (CENTAD); Delhi Society for Promotion of Rational Use of Drugs (DSPRUD) and Organisation of Pharmaceutical Producers of India (OPPI). The Committee also heard Shri Amir Khan and his team on the subject. Apart from the above depositions, the Committee also benefitted from articles and reports published in various journals and studies. The Committee considered the subject in detail spanning over 16 sittings and undertook a study visit to Chennai, Bengaluru and Mumbai to interact with the industry and other stakeholders and appreciate their view points on the subject.

3. A Press Communiqué was issued on 17th October, 2011 in the media and in response to the same, sixteen memoranda were received **(Annexure I).** The points raised therein have also been duly considered.

4. The Committee considered the draft Report on 10th July, 2013 and adopted the same.

5. The Committee expresses sincere gratitude to all the representatives of the various Departments / Ministries, organizations and individuals for placing before it their valuable suggestions, materials and information and also to contributors/publishers of various national and international journals/studies whose works were referred to during the examination of the subject.

SHANTA KUMAR
Chairman
Department Related Parliamentary
Standing Committee on Commerce

New Delhi;
*July 10, 2013*

## ABBREVIATIONS

| | |
|---|---|
| API | Active Pharmaceutical Ingredient |
| ANDA | Abbreviated New Drug Application |
| BIFR | Board for Industrial and Financial Reconstruction |
| CAGR | Cumulative Annual Growth Rate |
| CCI | Competition Commission of India |
| CGHS | Central Government Health Scheme |
| CL | Compulsory Licensing |
| CSIR | Council of Scientific and Industrial Research |
| DEA | Department of Economic Affairs |
| DIPP | Department of Industrial Policy and Promotion |
| DMF | Drug Master Files |
| DNA | Deoxyribonucleic Acid |
| DPCO | Drug Price Control Order |
| DSIR | Department of Scientific and Industrial Research |
| EU | European Union |
| FDA | Food and Drug Administration |
| FDI | Foreign Direct Investment |
| FEMA | Foreign Exchange Management Act |
| FERA | Foreign Exchange Regulation Act |
| FIPB | Foreign Investment Promotion Board |

| | |
|---|---|
| GMP | Good Manufacturing Practices |
| HAL | Hindustan Antibiotic Limited |
| IDA | International Dispensary Association |
| IDPL | Indian Drugs and Pharmaceutical Ltd. |
| IPA | Indian Pharmaceutical Association |
| IPR | Intellectual Property Rights |
| IT | Information Technology |
| M&As | Mergers and Acquisitions |
| MBP | Market Based Pricing |
| MCI | Medical Council of India |
| MNCs | Multinational Companies |
| MSF | Médecins Sans Frontières |
| NCE | New Chemical Entities |
| NDDS | Novel Drug Delivery Systems |
| NIH | National Institutes of Health |
| NLEM | National List of Essential Medicines |
| NPPA | National Pharmaceutical Pricing Authority |
| NPPP | National Pharmaceutical Pricing Policy |
| NRHM | National Rural Health Mission |
| OPPI | Organisation of Pharmaceutical Producers of India |
| PHI | Public Health Interest |
| PSUs | Public Sector Undertakings |

| | |
|---|---|
| R&D | Research and Development |
| RMSC | Rajasthan Medical Services Corporation |
| SEBI | Securities and Exchange Board of India |
| TNMSC | Tamil Nadu Medical Services Corporation |
| TRIPS | Trade Related Aspects of Intellectual Property Rights |
| MHRA | Medicines and Healthcare Products Regulatory Authority |
| UNICEF | United Nations International Children's Emergency Fund |
| UK | United Kingdom |
| USA | United States of America |

# REPORT

## INTRODUCTION

1.1 Public health has been an area of concern for all societies since time immemorial. Every society and government has tried to put in place mechanisms necessary to ensure that affordable medical treatment is available to all citizens at any given point of time. One of the imperatives required to fulfill the desired goal of an efficacious public health is to assure sufficient availability of quality medicines at reasonable price to the largest number of people. This objective assumes critical proportions in the context of our country where majority of our citizens are poor and expenditure on medicines constitutes nearly 70 per cent of the total health expenditure in India. Unfortunately, the situation becomes more emergent in view of the fact that nearly 80 per cent of the total medical expenditure is not covered by insurance or any social security.

1.2 Since the availability and affordability of quality healthcare is of paramount importance to our nation, the Committee decided to study the impact of Foreign Direct Investment in the pharmaceutical sector in India, with the opening up of opportunities for foreign players to invest in pharmaceuticals.

1.3 The Committee is convinced that a developed indigenous pharmaceutical industry is the *sine qua non* for ensuring affordable quality medicine to people at large and the Government must take all policy measures to develop and sustain a robust domestic pharmaceutical sector in the country.

1.4 As per Central Government Health Scheme (CGHS) data, high costs of branded medicines contribute up to 40% of an outpatient's bill. It is imperative that we produce effective and cheap medicines in ample quantities to cater to the demand of our vast population.

1.5 The Committee understands that a drug can be categorised as—chemical/generic, branded generic or patent drugs. The chemical name gives the atomic or molecular structure of the drug and is too complex for general use. So, an official body assigns a generic name to the drug. When the drug is packaged and given a brand name by a manufacturer or a distributor, the generic becomes branded generic. A patent drug is one on which the patentee gets exclusive manufacturing and marketing rights for a period of 20 years. Once the patent expires, other manufacturers can produce and market them as generics.

1.6 It is understood that generics are as effective as branded medicines in the treatment of most diseases. A study* evaluated the results of 38 published clinical trials that compared cardiovascular generic drugs to their brand name counterparts and no evidence was found that branded cardiac drugs worked any better than generic heart drugs.

1.7 Generic medicines are sold at lower prices as the generic manufacturers are not required to repeat clinical trials as is the case in new drugs and generally do not

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*Kesselheim et al. Clinical equivalence of generic and brand name drugs used in cardiovascular disease: a systematic review and meta-analysis. JAMA. 2008;300(21)2514-2526

pay for costly advertising, marketing and promotion. In addition, multiple generic companies are often approved to market a single product; this creates competition in the market place, often resulting in lower prices.

1.8 The lower price of generics is an effective instrument to provide access to health care to people at large. The following table showing comparative prices of some common-use medicines illustrates the situation:

(as on December, 2010)

| **Used as** | **Generic drug** | **Price** | **Branded Drug** | **Price** |
|---|---|---|---|---|
| Painkiller | Paracetamol | Rs 2.45 | Crocin | Rs 11.00 |
| | | | Calpol | Rs 10.70 |
| | Paracetamol syrup | Rs 9.00 | Crocin (syrup) | Rs 15.00 |
| | | | Febrex | Rs 20.50 |
| | Diclofenac sodium + paracetamol | Rs 4.40 | Diclogesic | Rs 19.40 |
| Antibiotic | Amoxycilin | Rs 13.20 | LMX | Rs 40.00 |
| | | | Remox | Rs 38.70 |
| | Azithromycin | Rs 41.80 | Azee | Rs 107.00 |
| | | | Azithral | Rs 128.55 |
| Anti-TB | Ethambutol | Rs 14.80 | Myambutol | Rs 15.30 |
| Vitamins | Folic acid | Rs 2.80 | Folivite | Rs 11.80 |
| | B-complex | Rs 1.80 | Becosul | Rs 11.00 |
| Cardiovascular (Blood Pressure) drug | Atenolol | Rs 7.00 | Aten | Rs 23.80 |

Source: www.health.india.com

***Pharmaceutical Sector in India***

1.9 India has emerged as an important source for supply of generic medicines for domestic consumption. It has also catered to the needs of other parts of the world where a guarantee of cheap and efficacious medicine is nothing short of a blessing.

1.10 The pharmaceutical sector in India has witnessed significant growth and has left an impressive footprint on the global pharma landscape. India now ranks third in the world in terms of volume of production (9.3% of the global share) and 14$^{th}$ in terms of value (1.5% of global share). It supplies affordable and high quality generic medicines to a number of developing and least developed countries of the world and has rightly been designated as the pharmacy of the South. Indian generic medicines have also been accepted in the regulated markets of the US and Europe.

1.11 The Indian pharmaceutical industry had 2000 players in the domestic market before 1970 which was largely dominated by multinational companies (MNCs). The position in the 1970s was such that 85 per cent of the drugs were manufactured/ supplied by MNCs and the remaining 15 per cent by domestic units. The situation underwent a complete reversal in the 1990s with MNCs share coming down to 15 per cent and that of domestic units rising to 85 per cent. The main reasons for this reversal can be attributed to various initiatives taken by the Government such as the Patent Act (1970), Foreign Exchange Regulation Act

(FERA) (1974), Drug Price Control Order (DPCO) and sectoral reservations for public sector and small scale sector to build up self-sufficiency. The Indian Patent Act, 1970, by refusing product patent and allowing process patent, encouraged domestic producers to manufacture generic drugs and ensure self-sufficiency in medicines. The DPCO governed the prices of all bulk drugs and formulations to ensure the widespread availability of medicines at reasonable prices. Further, owing to introduction of Foreign Exchange Regulation Act (FERA) in 1974, which required all MNCs to dilute their equity holding, the market share of MNCs declined during 1970-79. During the period 1979 to 1987, the production of bulk drugs by Indian players increased due to a surge in exports. This policy environment converted the Indian pharmaceutical industry from net-importers to net exporters.

1.12 The Committee notes that the economic reforms process initiated in 1991 resulted in lowering of tariff barriers and FERA was relaxed, diluted and replaced by the Foreign Exchange Management Act (FEMA). These reform measures opened a window of opportunity for Foreign Direct Investment (FDI) in the domestic pharmaceutical industry. With greater openness for investments, the Indian pharmaceutical industry with investments from abroad, grew faster at a Cumulative Annual Growth Rate (CAGR) of 15-16 per cent, during the period from 1987 to 2001, with bulk drug production surging due to high export demands. At the same time, the Government also started taking off drugs/formulations from the Drug Prices Control Order (DPCO) and by its 1995 amendment brought down

the number of drugs under price control to 74 resulting in larger number of drugs out of the purview of price control mechanism thereby making the Indian market more attractive for pharma MNCs. Amendments to the Patent Act, 1970 in 2005, replacing process patent with product patent, in compliance with its obligations under TRIPS, also created a positive environment for pharma MNCs to do business in the country.

1.13 The Indian drugs and pharmaceuticals sector has been enjoying an annual growth of 12-14% per annum during the last few years. This has helped the sector improve its international presence in a big way and it is a matter of pride that our country has come a long way from being a dependent nation, to becoming not only a self reliant country in the sector but also emerge as a major exporter of high quality and cheap generic medicines to every part of the globe. The country today has proven international quality standard capabilities which are evidenced in significant number of ANDA approvals, DMF filings, US FDA/UK MHRA approved manufacturing facilities/ bio equivalence centres of our pharma industry. As per data recently published by the Department of Commerce, there are more than 350 manufacturing sites endorsed by EU for their Good Manufacturing Practices (GMP) in India as on 30th April, 2013.

1.14 The Indian pharmaceutical industry produces drugs worth Rs.1 lakh crore (US$ 20 billion) out of which exports account for about Rs. 42000 crore and domestic consumption Rs. 58000 crore. The country meets 95% of its domestic demands through indigenous production covering almost all therapeutic categories

and imports only a few high technology products. It is satisfying to note that today we export drugs to more than 200 countries and vaccines and bio-pharma products to about 151 countries. The export growth rate is around 10% per annum. The major chunk of exports relate to generic drugs which India has been able to offer at competitive rate while maintaining desired quality. It is worth noting that over 55 per cent of drugs are being exported to highly regulated markets.

1.15 According to *Médecins Sans Frontières* (MSF), India is the main supplier of essential medicines for developing countries. Poor patients of the developing world depend mostly on generics. It is a well documented fact that 67 per cent of the medicine exports from India go to developing countries. Similarly, international procurement agencies for developing countries depend on Indian generic drugs for their health programmes. Indian generic drugs also accounted for approximately 50 per cent of the essential medicines that UNICEF distributes in developing countries. Besides this, 75-80 per cent of all medicines distributed by the International Dispensary Association (IDA) to developing countries are sourced from India. According to US Food and Drug Administration (FDA), today, nearly 8 in 10 prescriptions filled in the United States are for generic drugs. The use of generic drugs is expected to grow over the next few years as a number of so called blockbuster drugs would go off patent through 2015.

## FDI IN DRUGS AND PHARMACEUTICAL SECTOR: A STUDY

2.1 In recent times, concerns have been raised in many quarters about the possible erosion of our strength in generics manufacturing on account of mergers/ acquisitions/ takeovers of our big domestic pharma companies by pharma MNCs. The existing FDI policy permitting 100 per cent investments in green field and brown field pharma projects have been identified as the major reason behind these acquisitions/takeovers.

2.2 The Committee notes that out of 67 FDI investments till September, 2011, only one has been in green field while all the remaining FDI has come in brown field projects. The Committee finds that FDI brown field investments have of late been predominantly used to merger/take-over of the domestic pharma companies.

2.3 It has, however, been submitted before the Committee that the data on FDI equity inflows, maintained by the Reserve Bank of India, does not distinguish between greenfield and brownfield investments. Hence, it was not feasible to arrive at an accurate assessment of the response to greenfield FDI in the pharmaceuticals sector. **The Committee finds this argument naive and desires that the government should stop behaving like an ostrich but instead take cognizance of the ground reality. Absence of such a mechanism is a handicap for the government while formulating policies for the sector. It is, therefore, high time that suitable mechanism be established to keep track of the nature of Foreign Direct Investments (brownfield and Greenfield investments)**

**coming in the country. The Committee calls upon the Department to provide forth with the segregated data on greenfield and brownfield foreign direct investments made in the pharma sector.**

2.4 The Committee also notes the apprehensions expressed before it on account of recent spate of mergers/acquisitions/takeovers owing to brownfield investments by pharma MNCs in our pharma units. It has been argued that the business model of the giant pharma MNCs would cripple our generic manufacturing capacity as these acquirers would be more interested in promoting their business interests rather than serving public interest. It was feared that the growing dominance of the MNCs would cause us to relapse to the pre 1970 era when we imported 80 percent of our drugs requirement and the prices of these drugs were costlier than what prevailed in USA. All efforts made at that time for purchase of technology from pharma MNCs had failed.

2.5 Time and again the Ministry of Health and Family Welfare has proffered the suggestion that we need to exercise a regulatory check over companies in the pharmaceutical sector. It was observed that though India is strong in so far as production of generic drugs is concerned, the country has not yet reached a position to control the international market since it has a share of only two per cent in terms of international market value. The country still has a long way to go since the market is currently dominated by North America, Europe, and Japan. The continued mergers/acquisitions/takeovers of domestic pharma units would be a dampener in our efforts to become a market leader.

2.6 The Committee notes that the stated policy of the Government is to provide universal healthcare to our population at affordable costs. Despite implementation of various schemes and crucial interventions like the National Rural Health Mission (NRHM), sixty-eight per cent of the people are yet to be fully covered. This yawning gap has to be bridged in the shortest possible time. It was informed by the Department of Health that the health budget is proposed to be enhanced substantially in the Twelfth Plan. New health programmes like National Urban Health Mission were being planned under which the entire urban sector was to be covered. With ambitious programmes like NRHM and other proposed schemes, the requirement of medicines is expected to go up substantially. As a consequence, the price of medicines would go up with increasing demand blocking out the finances required for other components of health plan. The consequences would then be serious and unaffordable for the country.

2.7 The Department of Health and Family Welfare has expressed its reservation over brown field acquisitions. The Department has argued for some sort of regulatory mechanism that may be put in place at the time of giving permission so that issues of healthcare get adequately addressed.

2.8 The Department of Health and Family Welfare has expressed the concern that once the MNCs acquire a dominant position they would try to throttle all measures imposed on them in public interest like price regulation or an essential-medicines-only policy, by responding that they cannot operate efficiently in such circumstances. Further, when the Government would consider imposing

compulsory license, there are likely to be no takers, because there will be only a few or no Indian generic companies left.

2.9 Slowly, because of such dominance, or abuse of dominance, entry barriers for new companies will get set higher and higher — no young man or woman would venture to establish a pharma start-up unless he/she has deep pockets. Gradually, there would be a monopoly of around half a dozen big multinational pharma companies with no motivation to serve domestic interests, and no compulsion to comply with local government interests.

2.10 The Department of Industrial Policy and Promotion (DIPP), Ministry of Commerce and Industry in its 'Discussion Paper' dated August 24, 2010, which was primarily on Compulsory Licensing (CL), also expressed some apprehensions towards foreign acquisitions of the Indian pharmaceutical companies. The Department felt that such takeovers could lead to an 'oligopolistic market' where a few companies will decide the prices of essential medicines, adversely impacting the 'Public Health Interest (PHI)'. If large Indian companies having the wherewithal to replicate any patented molecule are taken over by MNCs, the 'oligopolistic' situation thus created and being strengthened by the exclusivity of products through product patent rights, will severely limit the power of the government to face the challenge of Public Health Interest (PHI) by granting CLs. In such a situation MNCs could well decide to sell only the high priced patented and branded generic drugs rather than the cheaper essential drugs, pushing up the drug prices and causing extreme hardship to poor patients.

2.11 Keeping in view these serious concerns raised, the Committee decided to examine the FDI policy thread-bare to appreciate the merits and demerits of the policy and focus on the difficulties, if any, noticed in the policy for their appropriate redressal. The Committee considers the availability and affordability of healthcare to one and all as a priority objective. Hence the following appraisal is made with this main objective.

***FDI Policy***

2.12 The seeds of liberalisation of Pharma FDI policy were sown in the 1986 Drug Policy. The Committee recalls that the drugs and pharmaceutical sector was opened to FDI in 1991. FDI/Foreign Equity, up to 51%, under the automatic approval route, was allowed in manufacture of drugs, medicines and allied products. The sector was further opened up in the year 2000, as prescribed by the 1994 Drug Policy, by permitting FDI up to 74%, under the automatic route. Further liberalization of the drugs and pharmaceutical sector took place in 2001 and the sector was opened up for 100% Foreign Direct Investment, in respect of drugs not attracting compulsory licensing or involving use of recombinant DNA technology and specific cell/ tissue targeted formulations. With effect from 23rd September, 2005, drugs manufacturing was freed from licensing and the sector has been placed fully on the automatic route for FDI since then.

2.13 The Committee notes that the recent spate in acquisitions/mergers of leading Indian pharmaceutical companies by multinational pharma companies resulting in

the transfer of ownership to pharma MNCs had adversely impacted the accessibility and affordability of drugs for the general public and therefore the Government was compelled to revisit the extant policy of automatic route for FDI in pharma sector.

2.14 Accordingly, the Arun Maira Committee was constituted to look into these concerns. Based on the recommendations of the Maira Committee Report, the FDI policy was revised and notified by DIPP vide Press Note 3 of 2011 which states that all cases of FDI, up to 100% for investments in existing companies (Brownfield investments) in the pharmaceutical sector would require prior approval from the Foreign Investment Promotion Board (FIPB). FDI, upto 100% in the Greenfield investment in the pharmaceutical sector would continue to be permitted under the automatic route.

2.15 The Department of Economic Affairs had constituted a Special Group to examine various matters of FDI policy formulations in Pharma Sector and to make recommendations. This Special Group considered the public health concerns in respect of FDI proposals in brownfield pharma companies.

2.16 Subsequently, after a meeting chaired by the Prime Minister on 3.12.2012, the following decisions were taken:

(a) 100% FDI in Greenfield investments in the pharma sector under automatic route would continue.

(b) For brownfield investment in pharma:

i. The Ministry of Corporate Affairs to assess the need for additional amendments to be made to the Competition Act to accord suitable powers to the CCI to impose suitable conditionalities on Mergers and Acquisitions (M&As) keeping in view the public health concerns. Additional amendments, if deemed necessary, would be referred to Parliament, to be incorporated with the existing proposal already placed before it, at the earliest.

ii. In the meanwhile FIPB shall continue to scrutinize proposals for FDI in brownfield pharma.

2.17 The FIPB will impose the following conditionalities, wherever necessary, while considering proposals for brownfield investments in pharma:

(i) The quantitative level of National List of Essential Medicines (NLEM) drugs production at induction be maintained for 5 years.

(ii) R&D expenses be maintained in value terms for 5 years, and

(iii) Complete information be provided on the transfer of technology, if any, into the investing company.

2.18 The Committee notes that the pharmaceuticals sector has been one of the major attraction for FDI. Over the years pharma FDI has grown substantially and there has also been fluctuation in the flow of investment. The Committee notes that from April, 2000 to December, 2012, FDI equity inflows, in the Drugs and Pharmaceuticals Sector, amounted to US $ 9,173.50 million (Rs. 45,980.03 crore). This constitutes 5.6 per cent of total FDI received during the said period.

***Acquisition of Indian Pharma Companies by Foreign MNCs***

2.19 The Committee notes that the pharmaceutical industry globally is undergoing a paradigm shift in the way it conducts business to sustain growth. It has been argued that with the research & development pipelines running dry and patents on many blockbuster drugs going off-patent shortly, pharma MNCs are venturing into acquiring strong generic manufacturing Indian pharma companies

by taking advantage of 100% FDI through the automatic route introduced in 2001. The major reasons ascribed for the MNCs rush to India is to utilise the well-oiled domestic marketing network of the Indian companies, to take advantage of the lax regulatory system prevailing in the pharmaceutical sector to earn huge profits and gain control of the existing export market of the Indian pharma industry. Other factors like big domestic market size and growth trends, cheaper operating cost, English-speaking skilled manpower, predictability in business environment, efficient IT infrastructure, sound legal and IPR framework, broad base of scientists and R&D capabilities as well as well-equipped laboratories have also played an important role in attracting FDI inflows into the country.

2.20 It has been brought to the notice of the Committee that in the last few years, the position on account of FDI in pharmaceutical sector had not been very comfortable. In fact, it has been alarming, to put it very mildly. It was highlighted that since 2006, there have been seven takeovers. These companies are: Matrix Lab, Dabur Pharma, Ranbaxy Labs, Shanta Biotech, Orchid Chemicals, Paras Pharma and Piramal Healthcare. The fact that all these companies have been taken over at valuations much higher than their actual value is extremely disconcerting.

2.21 The Committee understands that there are several factors that have contributed to the spate of brownfield investments in the pharma sector which not only include the inherent strength of the Indian companies in producing world class products at very low cost but also several factors having international ramifications. Developed countries are facing severe strain on their health budgets

and are looking at generic drugs to cut down health costs. Sixty one drugs worth US $ 80 billion will go off patent during the period 2011-13. The Indian pharmaceutical industry is all set to gain from the expiry of patents in some blockbuster drugs by producing their generic equivalents. India has the highest number of US-FDA approved plants outside the US. Most of these plants have multiple approvals from regulatory authorities in Canada, Australia and EU countries. Thus the MNCs stand to gain in multitudinous ways by brown field investments in the country.

2.22 The Committee notes that the market share of foreign companies in the list of top 10 Pharmaceutical companies in India has increased from 10.5% in 2004-05 to nearly 19% in 2010-11. The Committee was informed by the Department of Pharmaceuticals that as per NPPA's study on cost of products, the trend in price variation of pharmaceutical companies under all the three categories, viz., Category A [7 top domestic companies], Category B [7 top Multi-National Companies (MNCs)] and Category C [7 Major Indian companies acquired by MNCs] was almost similar.

2.23 DIPP has informed that out of a total of US $ 9, 173.50 million FDI equity inflows from April, 2000 to February, 2012, US $ 4, 781.00 million of the FDI has come through acquisition route while an FDI of US $ 4, 392.00 million has come in through other routes. Thus 52 per cent of the FDI in drugs and pharmaceutical sector has been used for acquiring stakes in domestic pharma companies. The

following table is illustrative of some major acquisitions/ takeover of domestic companies by pharma MNCs since the year 2006:

| Year | Indian companies | Multinational companies | Value ($ Mn) | Type |
|---|---|---|---|---|
| 2006 | Matrix Labs | Mylan | 736 | Acquisition |
| 2008 | Ranbaxy Labs | Daiichi Sankyo | 4600 | Acquisition |
| | Dabur Pharma | Fresenius Kabi | 219 | Acquisition |
| 2009 | Shantha Biotech | Sanofi-aventis | 783 | Acquisition |
| 2010 | Orchid Chemicals | Hospira | 400 | Business Buyout |
| | Piramal Healthcare | Abbott | 3720 | Business Buyout |
| | Paras Pharma | Reckitt Benkiser | 726 | Acquisition |

Source: Organisation of Pharmaceutical Producers of India (OPPI)

2.24 From the information furnished by the Department of Economic Affairs (DEA), the Committee learnt that the companies prefer the acquisition route since it is easier for them to step into a running business rather than setting up a new unit. The latter process tends to be lengthy as well as costlier since there are approvals involved in setting up business including, for example, land acquisition, labour, environmental clearance, etc. **The Committee finds this argument too simplistic. If the domestic companies mentioned above could start from scratch and become lucrative then there is no reason as to why a foreign pharma company cannot come and similarly do business. Moreover, their huge business experience and R&D base will always be handy to equip them for successfully competing in the shortest possible time.**

2.25 The Committee learns that pharma MNCs have paid exorbitant amounts for acquisitions/takeovers of Indian pharma companies. To cite an example, against a prudent valuation norm of 2-3 times, M/s. Piramal Healthcare was acquired by Abbott at almost nine times the sales turnover. Daiichi paid Rs. 737 for each share of Ranbaxy which had an intrinsic value of just Rs. 365 at the time of its acquisition. **The Committee wonders as to how MNCs are going to recover such huge costs. One possible way of doing so is to either concentrate more on manufacture and marketing of costly branded products or increase the prices of generic brands or it may resort to both the alternatives. In doing so, the pharma MNCs are likely to use the marketing and distribution network of Indian generic companies to push their costly patented/branded medicines and displace popular generic brands of the acquired company from the market.**

2.26 Often price hike and competition in the Indian pharmaceutical market have been cited as a major concern against MNC acquisition of Indian generic companies. However, the Committee is of the view that the real concern is about the technological and financial capability of Indian companies to bring new generic medicines including the generic version of patented medicines. All acquisitions, with an exception of Mylan, have been carried out by MNCs having business interest in originator drugs, and they have been using patents as a main strategy to curb competition. There were apprehensions expressed before the Committee that pharma MNCs may delay introduction of generic versions in the market or even

not introduce them at all. In the backdrop of such business strategy, they may even prevent the acquired entities from using flexibilities to introduce generic drugs in the market and serve the purpose of their parent company. Initial evidence is available in the case of Ranbaxy where Daiichi-Sankyo's, immediately after acquisition of Ranbaxy, withdrew all its patent challenges on Pfizer's blockbuster medicine Lipitor filed in more than eight countries. **The Committee is concerned about the shift of ownership of generic companies to the hands of MNCs that result in the change of the business model and the marketing strategy. In the case of acquisition, the acquired entity's business model is synchronised with the business model of the parent company whereby the acquired entity is not allowed to use flexibilities such as patent opposition or compulsory license to introduce new generic medicines. The withdrawal of all patent challenges by Ranbaxy on Pfizer's blockbuster medicine Lipitor filed in more than eight countries immediately after its acquisition by Daiichi-Sankyo is a case study by itself.**

2.27 While responding to the concern of the Committee on the issue of over-priced takeovers, the DEA informed that if Indian pharma companies are taken over at substantial higher valuation, the new owners would like to recoup their investments and earn maximum profits. However, it was further added that the guidelines in respect of valuations of non-resident investments into India are laid down by the Reserve Bank of India and notified under the Foreign Exchange Management Act (FEMA). The transaction has to be vetted by a valuation of the

Company by a category 1 SEBI registered merchant banker using the Discounted Cash Flow method. The price paid has to be at least this valuation in order for it to be in line with FEMA. Further, it is normal for investors taking control over any business to pay a premium to the existing promoters to ensure that the latter do not take away the business or offer competition in future. This is called 'non-compete fee' and is normally a part of the takeover agreement to afford a measure of economic certainty to the investor. This is a normal part of international acquisitions/takeover deals. The Committee was informed that apprehension about takeovers of Indian pharma companies 'at higher valuations than their actual value' may be misplaced. If the Discounted Cash Flow method of valuation is regarded as the actual valuation, FEMA allows that the acquisition can take place with this valuation as the minimum, which is what has happened in all the cases.

2.28 **The Committee is dismayed by this argument of the DEA that very high valuation is basically a premium to check competition from the promoters of the acquired company in future. This, coupled with the broad submission of DEA that the MNCs that have taken over Indian Pharma companies at substantial higher valuation have to recoup their investments and earn the maximum profits, hide the real intention of the pharma MNCs' high profile acquisition of big domestic pharma companies. The Committee recommends that the Department pierce the veil, take cognizance of the real threat, and take appropriate measures to ensure drugs security of the country.**

2.29 An important point made before the Committee was that developed countries have adopted a different pattern of healthcare service as a result of which the cost of their healthcare is extremely high. But now these countries are in the throes of economic recession and are looking for avenues to reduce their healthcare budgets. Replacing branded/ patented drugs with cheaper generics produced by Indian companies would certainly ease the burden on their economies. Since India is one of the major producers of generics in the world, FDI has been conveniently used for brown field acquisitions. According to FDA, in 2010 alone, the use of FDA-approved generics saved $158 billion, an average of $3 billion every week, of US government expenditure on public health. **The Committee is of the view that when a foreign company takes over a domestic company, immediate access of generics is available to that foreign company. The cost difference between some of the medicines that we produce here as 'generic' and what they produce there as 'branded' is sometimes as high as 80 to 85 times. This results in a win-win situation for every player, except us. When a foreign company acquires our domestic company, it exports our generics there and makes a huge profit. But if the same generic is sold at the higher price in India, the Indian public stands to lose and this is an area of concern. The Committee is of the strong opinion that any such attempt to sell generics at higher cost must be completely thwarted and the Government must establish a vigil on any such misdemeanour.**

2.30 The Committee observes that the entry of MNCs in the generic space is a strategic shift in their business model. The acquisition of generic companies is not only a tool for implementing the strategic shift, but also a smart move to fast track their entry into the generic space. The Committee notes that the Indian generic industry has emerged as the biggest ever challenge to the MNCs. The Indian companies are competing with them not only in the global market, but also in their own backyards through patent challenges and exports of low cost high quality medicines. **The Committee is deeply concerned over the spate of mergers/acquisitions/takeover of domestic pharma companies. It seems that the old hackneyed route for monopolists to buy out competition in order to prevent the emergence of low price market is in full play. The Committee is unhappy over these developments since the real danger of the 100 per cent FDI and the selling/takeover of Indian companies is the decimation of competition as well as capabilities.**

2.31 The Committee finds it logical that a commercial enterprise will aim to recover its investment as soon as possible. The MNCs' time tested way of improving returns is higher prices. The Committee notes that the innovation for low cost pharmaceuticals is essentially driven by domestic companies. It has never been the strength of the MNCs. As foreign companies may not be interested to pursue low cost pharmaceuticals, it would result in lesser innovation for low cost pharmaceuticals. The Committee fears that as more companies are acquired and as the foreign companies shift their focus from the low priced domestic market to

remunerative global markets, the supply to domestic market will become secondary. The increasing dominance of the foreign companies will hit domestic companies in two ways. Firstly, the market dominance (time secured in the doctors' chambers for detailing their products) will lead to more prescriptions for the foreign companies, driving away the domestic players from the Pharmaceutical Sector. The domestic companies took three decades to secure a position of eminence in the doctors' chambers. This will be lost soon, if the foreign companies were to have unbridled freedom of acquisition. Secondly, the originator companies having entered the generic space and obtained product registrations held by the domestic companies in third countries will use their dominant position to throttle other domestic companies in the global market, impacting the export performance of domestic companies. **The Committee shares the concern that serial acquisitions of the Indian generic companies by the MNCs will have significant impact on the competition, price level and availability. It could incapacitate the domestic industry and slow down new investments and employment generation by the domestic companies. All these in turn could adversely impact the availability and access to medicines at affordable prices. A few more takeovers of this kind may destroy the benefits arising out of India's generics revolution. This may even be a good strategy for the 'innovators' to 'silence' the generics frontrunners, thereby, retaining their innovation foundations while acquiring huge generic potential.**

2.32 The Committee notes that so far MNCs have targeted India's leading generic manufacturers having the technological capability to introduce generic medicines in the shortest possible time. This would result in the elimination of generic companies having technological capability to introduce generic medicines to meet the public health needs of India.

2.33 The basic rationale behind inviting FDI inflow has been the creation of manufacturing capabilities, introduction of new technologies and employment generation. On a specific question as to whether the present FDI policy for pharmaceuticals sector has brought the desired benefits in terms of capacity augmentation, technology acquisition, employment generation etc. in the pharma sector, the Committee was disappointed to note that the Department of Pharmaceuticals had no such specific information available with it despite it being the administrative Ministry for the sector. Instead the Department deviated from the query by mentioning that the Indian Pharmaceuticals Industry has shown a robust growth of around 14% from a turnover of about Rs. 71000 crores in 2007 to over Rs. 1 lakh crores in 2009-10. **The Committee is of the view that the Department of Pharmaceuticals should be more proactive about the conduct and dealings of pharmaceuticals companies in the country. This would enable it to prepare appropriate policy measures balancing the growth of pharmaceutical industry in the country as well as ensuring due discharge of social responsibility by the pharmaceutical industry towards public health.**

***Research and Development***

2.34 The Committee is of the view that FDI must promote continuous improvisation in technology and bring in innovations. It must help create and also strengthen local capabilities to augment and diversify production; bring in best practices that would help add value to exports; and enhance the complementarities and linkages between economic sectors by increasing employment opportunities and knowledge base.

2.35 The investment in R&D by the domestic and foreign companies for the last three years is as per the table below:

| **Year** | **Growth in R&D Expenditure (Rs. Crore)** | | **R&D Expenditure as % of sales** | |
|---|---|---|---|---|
| | **Domestic companies** | **Foreign companies** | **Domestic companies** | **Foreign companies** |
| Mar 2008 | 2772.63 | 700.18 | 4.78 | 2.86 |
| Mar 2009 | 3316.14 | 846.05 | 4.89 | 3.84 |
| Mar 2010 | 3342.32 | 934.40 | 4.50 | 4.01 |

Source: Department of Pharmaceuticals, Ministry of Chemical and Fertilizers.

2.36 When asked about the details of funds infused in pharmaceuticals R&D through the FDI mode during last three years, the Committee was informed that between the financial years 2010-11 and 2012-13 (up to December), FDI, amounting to Rs. 524.25 crores was brought into the sector of 'Research & Development'. It was also informed that separate data on FDI brought in specifically for R&D in the pharmaceuticals sector, is not maintained by the Reserve Bank of India. The Committee notes that the pharma industry has attracted FDI to the tune of Rs.18678.11 crore during the last three years out of which less

than 3 per cent was the total FDI share in pharma R&D during the period. **It can be deduced from the figures that the FDI inflow into Research & Development of the Pharma Industry has been totally unsatisfactory. The Committee expresses its dissatisfaction that despite the profusion of FDI into the pharma industry in general, R & D in pharma has not got any significant benefit in particular. This trend is indicative of the fact that FDI is primarily being used to strengthen the business network of pharma MNCs and in keeping the domestic pharma companies in a subservient position without adding anything positive to the Indian health scenario. It is high time the Government took concrete steps to attract and ensure substantial amount of investments into R&D sector of the pharma Industry with special thrust on tropical diseases.**

2.37 The Committee notes that innovation in the Indian pharma industry has been more or less restricted to process chemistry and reverse engineering capabilities whereas R&D efforts have served negligibly to the country's needs. Though R&D activities have diversified, Indian pharmaceutical firms have yet to prove their competence in innovating new products. Development of New Chemical Entities (NCE) is a rarity in the Indian pharma industry which means there is a serious lack of originator companies in the industry.

2.38 The Committee takes note of the fact that the efforts of both Ranbaxy and Dr. Reddy's in developing improved generics and Novel Drug Delivery Systems (NDDS) helped in opening the doors for domestic pharma units to collaborate with

the pioneer producers but the partnership model has not always worked properly. India is fast emerging as the hub for contract research and manufacturing with a number of pharmaceutical majors establishing joint ventures with Indian generic producers. Nevertheless, these successful forays by Indian pharmaceutical firms would have to be assessed in the context of their role in providing access to medicines at affordable prices. **The Committee finds that acquisitions/collaboration of local companies has unfortunately forced R&D priorities to be increasingly set in tune with global trends neglecting R&D on 'tropical diseases' and also capability development of NCEs in this process.**

2.39 The other feature noticed in our FDI inflow towards R&D has been of 'out-licensing' where the Indian company takes some leads to pre-clinical stage and then strikes a deal with an MNC which then will have the right to market that compound in a particular market if all tests are cleared. *The Indian company gets ‘milestone payments’ for each stage of clinical trials and compound approval. This way a foreign company operating in India can transfer early research successes to its parent company abroad and the same drug can then be sold to Indians at very high global prices. With limited experience and high costs associated with bringing a drug to the market, Indian players have traditionally shied away from drug discovery, or in a few cases, out-licensed molecules to multinational companies at early stage of development. The current FDI policy is heavily tilted

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* Abrol et al. Globalization of the India Pharmaceutical Industry: Implications for Innovation. IJIE Vol. 3, No. 2, July 2011, pp 327-365.

in favour of MNCs and, as a policy tool, it has not been able to help create a sustainable pharma research base or drive capacity creation in R&D for domestic pharma units in a significant manner. It is evident that only a handful of firms have been able to increase their R&D investments in a significant way. It is a little uncomfortable to note that R&D expenditure of the top fifteen Indian pharmaceutical firms is nowhere near the expenditure being incurred by the companies of Israel and Europe who are also operating in generics field.

2.40 Another disconcerting fact regarding the nature of R&D has been noticed in the greater collaboration of pharma MNCs with our domestic companies in the area of clinical trials which is mostly for phase III trials. The Committee is a little surprised about the basis of such collaboration since our domestic pharmacompanies are still in the infancy or phase I stage as far as core competencies for clinical trials are concerned. Our efforts for compound development and testing are very small in comparison to world standards. A few large domestic pharma units have confined their pursuits of drug discovery and development to finding a new drug within an existing family that has been discovered rather than going for cutting edge-drug innovation. In view of the structural difference in approach towards drug development as well as in core competencies between pharma MNCs and our domestic companies in the area of clinical trials, the Committee wonders what benefits this type of collaboration would yield to our domestic pharma companies in terms of development of our competencies in this critical area. **The Committee is of the view that such**

**collaboration is being valued more for the patients India can provide as guinea pigs for clinical research rather than for competencies**. **The Committee expresses its displeasure over such alliances of convenience**. There are many media reports about poorly run and unethical trials that have resulted in health problems and even in the death of some trial participants, who were often signed up for the clinical trial without their knowledge. The apex court in its recent judgment rapped the Government for its failure to stop illegal trials by MNCs. Drawing attention to uncontrolled clinical trials, the Court directed the Government to manage the menace of poorly regulated trials on a war-footing. **The Committee also condemns these unethical practices being pushed by pharma MNCs. Needless to mention such a situation has arisen owing to the absence of a strong regulatory framework. The Committee recommends that the Government frame guidelines for safe clinical trials and ensure its strict implementation. It hopes that the government will take appropriate measures to address the concerns regarding clinical trials, while not losing sight of the need to develop the competency of our pharma units to undertake clinical research for development of new drugs.**

2.41 The Committee understands that clinical trials and tests are a crucial part of drug innovation and development. These trials hold enormous potential for benefiting the domestic drug industry and ultimately the common man. It is a matter of immense concern that India despite being a leader in the pharmacy world lacks the capability of conducting trials and tests. The Committee notes that

several medicines in India are being sold without having undergone clinical trials to check their safety. This serves as a dent to India's stature as the global pharmacy and hampers the flow of exports, as well as places the domestic population under immense risk. **The Committee desires that world class infrastructure and facilities as well as adequate funding be made available to facilitate domestic companies in developing capacities for trials and testing.**

***Technology Transfer***

2.42 The Committee has noted earlier the reluctance of foreign pharmaceutical firms to transfer technology to our pharma industry which adversely affected its growth and development. The situation has almost remained the same even after the opening of the pharma sector to foreign direct investment. A data regarding intensity of R&D and royalty payments for the period 2006-08 available on Centre for Monitoring Indian Economy (CMIE)'s website suggests that pharma MNCs are spending much less on R&D as compared to domestic firms. Also, most of our domestic pharma units have paid extremely small or no royalty on account of technology transfer which is indicative of the fact that our pharma industry has not gained in terms of technology on account of FDI in the sector. **The Committee feels that effective technology transfer is critical to success in the pharmaceutical industry. It is therefore imperative that the Government takes effective measures to promote development of technological capabilities in our pharma units. The various collaboration models with pharma MNCs have certainly helped some of the domestic units improve their production**

**capabilities by enforcing Good Manufacturing Practices but these business models have no significant impact on the technological capabilities of the local pharma firms.**

2.43 **The Committee is convinced that FDI has failed to bring about any real change in the existing pharma R&D environment as domestic pharma companies are still to gain the competence and capacity to achieve cutting-edge drug innovation by carrying a new compound through all stages of research up to marketing. After all these years of FDI in drugs and pharmaceuticals sector, India is still weak in laboratory stage drug discovery. As per a study*, during the period 1999-2009, out of a total 166 disease type-wise R&D activities being conducted in India only 9 were undertaken for the neglected diseases (Type III), 10 for Type II diseases and the rest catered to Type I diseases which are pre-dominantly life-style diseases having a huge market in the western hemisphere. Similarly, during the period 2007-09, out of a total 186 clinical trials of type-wise diseases, only 5 Type III diseases were under clinical research whereas 175 Type I diseases were under clinical safety trials. The Committee is anguished over the pattern of research that has emerged on account of collaboration between foreign pharma companies and the domestic pharma companies which serves western markets rather than the needs of the local population.**

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* *supra* para 2.39 pp 37.

2.44 With the advent of product patent regime, indigenous development of new drugs has become absolutely vital for the survival of domestic companies in the global pharma market. Investing in and enhancing R&D capabilities would ensure long term stable growth for the domestic industry. **The Committee notes that lack of public funding is a serious issue hindering the R&D efforts of the industry. Timely and adequate public funding is paramount to discovery of medicines which should be made available at cheaper costs. Pharmaceutical research is not only an expensive venture but also a risky one. The rate of failure is relatively high. The risk averting instinct of our country's R&D professionals needs to be addressed.**

2.45 While talking about R&D, it is equally important that efforts are made towards attaining world class standards of R&D in the pharma sector. The Committee is convinced that this can happen only with State intervention and not by merely opening the sector to FDI. **The Committee desires that adequate public funding must be earmarked for R&D in the pharma Sector so that technological capability is created to make us capable to discover new molecules and become self sufficient with regard to API / intermediates. The focus of R & D should be on tropical diseases and its cures as well as on improvement of the quality of the generics produced by us.**

***Employment Generation***

2.46 The Committee has been given to understand that FDI has neither led to job creation nor creation of gross fixed assets. In the last five years the gross fixed

assets was worth of Rs.54, 000 crores. The MNCs which have taken over these companies have added assets worth a mere Rs.3000 crores and FDI flows have merely resulted in change in ownership with no addition to manufacturing capacity. Indian Pharmaceutical Association (IPA) informed the Committee that the track record of investment in the pharmaceutical sector over the last 15-year period (1995-2010) shows that the MNCs have contributed only five per cent of the gross fixed assets creation, i.e. Rs.3,022 crore as against Rs.54,010 crore by the domestic companies.

2.47 **The Committee is of the view that FDI flow into brown field projects has not added fresh capacity in terms of production, distribution network or asset creation to the desired level. As a result, significant strides have not been made in creating fresh jobs and transfer of technology. The Committee desires that the Department concerned must take desired steps to come up with optimal policy formulation in this regard.**

**THE ROAD AHEAD**

3.1 The Committee undertook an analysis of the effects of such takeovers. It noted that nearly 19 per cent of the markets were already controlled by the pharma multinational companies, which was a significant share since even five per cent share can impact the availability, price, etc. If another top three Indian companies are acquired by the MNCs, their share would rise to 32 per cent and on acquisition of next rung of eight companies, their share will go over 46 per cent which, undoubtedly, is an alarming proposition. It was pointed out that in the last five

years, the market share of pharma MNCs has grown from 10.5 to nearly 19 per cent. **The Committee fears that these MNCs can change or tweak the product mix and can go from producing generics into branded or even more expensive patented medicines. Its direct impact will be on the availability of the cheapest priced generics for Indian population which may decrease substantially. There is also the fear that a foreign company may not easily agree to compulsory licensing which will not be the case in an Indian company. Once a foreign company takes over an Indian company, it gets the marketing network of the major Indian companies and, through that market network, it changes the product mix and pushes the products which are more expensive and there is no provision to stop an MNC from changing the product mix. Internationally, because of its huge network and access to other markets, it can block our smaller domestic companies from establishing their presence in the global market.** The Committee is aware that the Indian pharma market is very fragmented and there are very few companies which are operating at the top level. It is the big companies which could have been the major game changers but these big companies were being taken over. Our smaller companies with their meagre resources will find it difficult to establish their potential in the international market. Thus, there will be no challenge for these pharma MNCs and this development has inherent dangers.

3.2 The Planning Commission and the Department of Pharmaceuticals submitted before the Committee that it was too early to assess the consequences of

FDI in brown field projects and the consequential prices in the market. However, after examining the effect of FDI on prices of medicines on the basis of whatever little evidence was before them, it has been noticed that so far, prices of medicines have not gone up as a result of FDI. **The Committee is of the view that though the prices may not have increased significantly now but there is a threat that once our domestic capacity is crushed under the weight of the dominant force of multinational pharma companies, the supply of low priced medicines to the people will get circumvented. The Committee cautions the Government to remain vigilant and recommends establishing mechanisms to prevent increase in prices of medicines.**

3.3 The future action of pharma MNCs is unclear but it is important to put in place all mechanisms to avoid any adverse impact on availability of cheap medicines. **The Committee is of the opinion that foreign investments *per se* are not bad. The issue was not about promoting FDI for takeover/requisitions of domestic pharma units but to promote more investments into the pharma industry so that there is greater research, adequate availability of medicines and more competition which will ensure affordable and accessible medicines. It is important to ensure the presence of sufficient number of companies so that there is competition which will keep a check on the prices of drugs. The decimation of the strength of local pharma companies runs contrary to the above desired position since there would be few or no Indian companies left having necessary wherewithal to manufacture generics once a drug goes off-**

**patent or comply with a Compulsory License (CL). The permission to allow acquisition/merger would finally leave generics production in the hands of pharma MNCs who would never like to promote them in comparison to their branded medicines. The Committee expresses its dissatisfaction with such a development.**

3.4 The Committee takes cognizance of the reports emanating in media that the European Commission, the EU's anti-trust regulator, on the basis of an enquiry instituted in 2009 has decided to impose fines on Ranbaxy and eight other generic drug manufacturers for limiting access of cheaper generic drugs to the consumers. The whole episode is the result of so-called pay-for-delay deals wherein Ranbaxy and other generic drug companies allegedly went into an agreement with brand name drug manufacturers not to deliver cheaper drugs to the market for monetary consideration. **The Committee is of the view that this is an example of unfair trade practices adopted by pharma MNCs where they first influence generic manufacturers to go slow and then buy the generic drugs competition to completely stop their movement in the drugs market. In this process, it is the common man who loses his basic right to affordable medicines.**

3.5 The Committee gathers that to ensure the end objective of access to medicines at the lowest possible price for all, a lot of work is required to be done on the other side of the chain. It is not dependent on the acquisition side of the chain alone. Apart from devising modalities to prevent damages that might accrue due to acquisitions, we also need to be more effective on price controls and anti-

consumer practices. In this scheme of things, the Government has to play an active role by encouraging Public Sector Companies to:

(i) invest in pharma innovations relevant to our country;
(ii) use the public distribution system effectively for providing medicines to poor people; and
(iii) engage in production of essential drugs.

3.6 **The Committee has been informed of several irregularities in the distribution and retail sale of medicines. It emphasizes the need for the Government to step in and revamp the distribution system so that people have access to good quality medicines. The Committee had occasion to study the functioning of the Tamil Nadu Medical Services Corporation (TNMSC) and the Rajasthan Medical Services Corporation (RMSC) and it found that these agencies have efficiently procured generic medicines at prices 50 to 60 times less than the retail prices of market leaders. The Committee recommends that the Government examine the Tamil Nadu/Rajasthan model and suggest a model scheme for providing affordable medicines to one and all in the country.**

3.7 The Committee firmly believes that regardless of free market, price control of essential medicines must be retained and strengthened. The Committee was informed about the price control mechanism which has been in place to safeguard the interests of consumers to ensure that the price of drugs does not rise more than 10 per cent in a year. Again the Compulsory Licensing mechanism also ensures the adequate availability of a drug at low price to people in the market. The

Committee notes that the Government has come up with the National Pharmaceuticals Pricing Policy (NPPP) 2012 and has put all 348 drugs in the National List of Essential medicines (NLEM) 2011 under price control. The NPPP spells out a new method for determining the price ceiling, called market-based pricing (MBP). Concerns have been raised that this pricing model leads to unreasonable super-profits being earned by pharma companies, inefficiency and market distortions and also unethical behaviour. **The Committee recommends the Government take all measures to ensure that essential medicines are affordable to the common man. It should come up with a viable method of price fixation which primarily serves the above purpose. This price control mechanism should incorporate the instrumentality of fixing the launch price of the drug at the time of its introduction, rather than feel helpless in adjudging the launch price on objective criteria. The Committee feels that cost-based pricing model may be considered for the purpose.**

3.8 **The Committee emphasizes the need for widespread promotion of quality generic medicines in the country. Since generics are as effective as branded generics and are cheaper, the Government must take all measures to protect the domestic generics industry. This is more important in view of the fact that a large section of our population is deprived of medicines on account of their high cost. It goes without saying that unbranded generic medicine is the only hope for the teeming millions in our country and also other parts of the globe. Any policy that adversely affects, howsoever remotely, the generics**

**capacity of our country must be discarded. The Committee believes that we must only promote consumption of unbranded generic medicine in the country. The Government has put the onus on Medical Council of India (MCI) for this task which is not sufficient. The Committee recommends that Government bring in legislation to make it legally binding on all the doctors to prescribe generic drugs in their prescriptions and/or clearly prescribe generic equivalents of branded medicines. This will not only give a spurt to our domestic pharma industry consisting of predominantly small and medium units but also ensure access to medicines to all in the real sense. Documentaries/Visual advertisements/short films should also be made by Films Divisions to bring awareness about generic medicines in rural areas of the country.**

3.9 It has been further stated that though India is a signatory to the TRIPS Agreement, there are pressures that it should go beyond the TRIPS Agreement, particularly in the healthcare sector. Department of Health and Family Welfare elaborated that with a sizeable presence of pharma MNCs operating in our domestic market and exporting the product from India for feeding their own domestic market, they would certainly acquire a very strong voice putting the country under pressure on issues relating to TRIPS Agreement which may not be in its interest. **The Committee shares the concern of the Department. The Committee finds that pharma MNCs are extremely opaque about revealing the cost of a patented drug but are also more often than not, trying to hold on**

**to patents even after the expiry of the drug by tweaking the composition of the drug, a process commonly known as evergreening. The recent Supreme Court judgment denying patent right to Novartis, a multinational pharmaceutical company, for continuing patent rights over Glivec, a potent anti-cancer drug is a pointer in this direction.**

3.10 The Committee is satisfied to note that various flexibilities as well as some safeguards have been provided under TRIPS which can be used to mitigate the anticipated negative impact on drug prices and on access to drugs. These have been duly incorporated in our Patent Act to ensure quality affordable medicines to people at large. The important safeguards under TRIPS which have also been incorporated in the Patents Act are: (i) compulsory licensing, (ii) parallel importation and (iii) provisions for early working (often referred to as "Bolar provision"). A special case of compulsory licensing is 'Government use' (or a compulsory license for public non-commercial use) for the purposes of its own use or for distribution in any dispensary, hospital, or other medical institutions. Data protection, but not data exclusivity has also been rightly provided.

3.11 The Committee is appreciative of the fact that a compulsory licence (CL) was issued under Section 84 of the Patents Act to the Indian generic drug company Natco Pharma Ltd for Bayer's anti-cancer drug Sorafenib. The CL breaks Bayer's monopoly over the drug which was being sold for Rs. 2, 80,000 a patient a month. The CL enables Natco to make the drug available at as low a cost as Rs.8, 800 a month. The fact that this is the first CL issued in India is in itself a major step and

can be a precedent for many more similar CLs in the future. **The Committee desires that more such drugs must be identified on continuous basis and their prices be reduced suitably by utilizing the various instruments like compulsory licence, etc. and other safeguards envisaged under TRIPS and our Patent Act. The Committee is of the view that the availability of patented drug to the needy is more important than the interest of the patent holder.**

3.12 The Committee notes that the patentee companies are highly secretive in terms of sharing information about the research cost which they claim to be the major factor behind the high price of a drug. It is a lesser known fact that the entire research that leads to discovery and development of a new drug is often not completely financed by the pharma companies. National and international institutions like Council for Scientific and Industrial Research (CSIR), National Institutes of Health (NIH) are public institutions funded by tax payers monies and philanthropic donations and grants. It is the funding by these institutes to new research that predominantly influence discoveries and development of new chemicals and drugs. These institutes are not profit-driven but infused with the objective of extending the benefits of research to ensure a long and healthy life for all populations. The *leit motif* is long term, basic scientific research rather than sharply focused quests for treatment and disease prevention.

3.13 **The Committee is of the considered view that the Government must take up the TRIPS agreement afresh at an appropriate forum and collectively work with world governments to ensure that flexibility in periodicity of**

**exclusive manufacturing right to a patentee company is introduced in the patent regime depending upon the amount of expenditure incurred by the patentee as well as the extent of its contribution in the R&D.**

3.14 The Department of Scientific and Industrial Research (DSIR) informed the Committee that most of the domestic pharma companies acquired by MNCs derived their technologies from CSIR laboratories. The domestic companies were provided tax breaks and subsidies which aided their stupendous growth. But now with the takeovers, all the benefits have accrued to the foreign companies. By partnering with these scientific institutions at the ripe moment, these pharma MNCs declare the new molecule as their innovation and get patent rights on them. **The Committee takes serious note of this matter and desires that such benefits should ultimately serve the interest of the public rather than benefiting MNCs**. **The Committee recommends the Department draft some mechanism whereby the benefits availed and the cost of the brand value acquired owing to such governmental assistance may be recovered from these pharma companies on their divesting of the shares for money.**

***Revival of pharma PSUs***

3.15 Medicines have become so necessary in our healthcare system that medicines need to be seen as public goods which are essentially characterized by non exclusivity. In India where more than half the population does not have access to affordable healthcare and 70 per cent of the total cost of treatment is on account of medicines, it is imperative that medicines be considered as public goods.

3.16 The Committee feels Public Sector Pharma Undertakings will see to the purpose of non exclusivity and universal availability of medicines. However, the public sector pharma undertakings such as IDPL and HAL are in dismal financial condition. Both of them have been declared sick by the BIFR. The Committee observes that inadequate policy measures and mismanagement contributed to the collapse of the public sector units. **The Committee feels that these PSUs served the public in terms of availability, accessibility and affordability of medicines in the Indian context. They need to be revived, re-strengthened and made dynamic and healthy so that generic medicines and vaccines are produced in larger quantities and made available to the masses at reasonable prices. The Committee also feels there is an urgent need to investigate the reasons behind the poor performance and near-closure of PSUs so as to address the issues and to ensure that resources are utilized in the appropriate manner. The Committee observes that the absence of a robust public sector health service has impeded the universalisation of healthcare. In a situation when the private sector fails to step in and address the health needs of this country, the public sector would be a credible system to cater our growing health needs. A robust public sector would ensure self-sufficiency and shield the pharma sector from adverse effects of market dynamics and investment policies.**

**CONCLUSIONS**

4.1 During the examination of the quality and quantum of FDI in pharmaceutical sector the Committee found that FDI inflows have predominantly been in brown

field pharma projects in the country with no substantial qualitative improvement in R&D or capacity creation.

4.2 The Committee feels that the current spate of takeovers/acquisitions would lead to a situation where the supply of medicines to domestic market will become secondary as pharma MNCs would shift their focus from low priced domestic market to remunerative global markets. Once taken over, the companies in question could bring a completely different product-mix, which could change the production profile of low priced generics *vis-à-vis* branded medicines. This could adversely affect the supply of low-priced generic drugs, which, in turn, would make health care and life saving medicines out of reach for a large part of our population. The possibility of these entities working in tandem, as a cartel, to exploit the Indian market, cannot be ruled out. The pharma MNCs having entered the generic space and obtained product registrations held by the domestic companies will use their dominant position to throttle other domestic companies in the global market, making exports from domestic companies difficult. **The Committee notes that the adverse effect of takeover/acquisition is starting to show as the export performance in dollar terms during 2012-13 has not been satisfactory as compared to the past two years. The targeted figure of US $ 24 billion exports would be difficult to achieve by the projected time-line of March, 2014. The Committee desires that appropriate actions are taken by the Government to arrest the deteriorating performance of our pharma industry on export front.**

4.3 The Committee is of the view that the present FDI policy regime cannot prevent foreign control over local pharma companies, because the regime itself allows 100% FDI albeit on FIPB route in brown field pharma companies. The Committee finds the situation disconcerting since FDI has not brought any real benefits to our pharma industry as noted in the preceding paras except transfer of ownership of big domestic pharma companies into foreign hands. It also shares the apprehensions raised in various quarter regarding possible loss of our prowess in generics medicine through acquisitions/merger/takeovers of our domestic pharma companies by pharma MNCs through FDI route.

4.4 **The Committee also notes the danger arising out of FDI in brown field pharma projects to the entire health and IPR framework of our country in terms of access and affordability of medicines, domination and elbowing out of our pharmaceutical industry comprising of predominantly small and medium pharma units, undue demand and pressure on TRIPS arrangements, etc. The Committee is, therefore, of the considered opinion that the Government must impose a blanket ban on any FDI in brown field pharma projects. It strongly recommends that the Department take all measures to stop any further takeover/acquisition of domestic pharma units. This necessity becomes more telling in view of the fact that the pharmaceutical industry is not like any other industry/business. It is one sector of the economy which has to be dictated by public good rather than foreign investments, profit and revenue.**

4.5 It goes without saying that our pharmaceutical industry has grown without outside help. It has been our own policies and enterprise that has made our pharmaceutical sector leave an indelible imprint the world over. **The Committee feels that FDI in brown field pharma sector has encroached upon our generics base and adversely affected our pharma industry.** It has been noted earlier that sixty one drugs worth US $ 80 billion will go off patent during the period 2011-13. This window of opportunity for our thriving pharmaceutical industry might be jeopardized if we continue allowing FDI in brown field pharma sector. Moreover, when 95 per cent of our domestic demands are met internally, the increase in our domestic market share of pharma MNCs is a clarion call to preserve our inherent strength. Any reliance of our population on foreign pharma companies would adversely affect the access and affordability of drugs in the future.

4.6 The fact that the need arose to place brown field proposals under the FIPB route from the earlier automatic route puts a question mark on the efficacy of FDI in brown field pharma projects. It raises serious questions about the existing FDI framework for pharmaceutical sector in attaining the objective to enable Indian pharmaceuticals industry to play a leading role in the global market and to ensure abundant availability, at reasonable prices within the country, of good quality pharmaceuticals of mass consumption laid down in the National Pharmaceuticals Policy. **The Committee feels that introduction of FIPB approval mechanism is a feeble attempt which would not be able to measure upto the challenges posed by this route. The Committee is also of the view that restricting the**

**inflow of FDI however can only have a limited impact. It sincerely believes that to ensure availability of essential drugs to the common man, all forms of production, pricing and distribution of pharmaceuticals have to be effectively monitored by the Department of Health and Family Welfare themselves or through regulations or through an independent regulator. It is always convenient to monitor through a single agency than to allow multiple regulators working in different directions with different mandates without much accountability.**

4.7 **The Committee, nevertheless, agrees with the present FDI policy on green field pharma projects permitting upto 100 per cent under automatic route. The Committee desires that the Department undertake consultations with all stakeholders to create favourable conditions to promote green field investments in pharma sector. It is also of the view that FDI in green field pharma projects may be automatic but subject to some conditions. It must be ensured that the failure to comply with provisions should attract penalty including cancellation of registration. Foreign investors must also bring in new technology for local production of Active Pharmaceutical Ingredient (API) manufacturing from basic stage. It is important to create API capabilities since we heavily depend on other countries, especially, China for our API requirement and our medical security is at stake. Sectoral regulations must ensure that the foreign companies set up indigenous production of patented medicines which are totally imported today.**

4.8 **The Committee recommends that the concerns/ recommendations/ observations made by it in the above paras may be spelt out as policy parameters and placed in the public domain so that the investors are fully aware of the compliance requirements. Any uncertainty of outcome or piece-meal approach to approvals may cause investor anxiety. Public health concerns should be addressed through pharma-related supporting institutions, laws of the land, structures and regulations.**

4.9 The Committee would like to subscribe to the market philosophy, which is imbued in the universal human rights norms as it attaches importance to serving public health and the global poor. The market fundamentalist may mock at such an approach and target at eliminating or altering domestic medicines policies aimed at facilitating access to essential medicines by poor by decrying them as unnecessarily restrictive non-tariff barriers to trade. The pharma MNCs through their respective national governments try to remove them through multilateral or bilateral free trade agreements. There have been instances where these trade agreements also restrict government's capacity to stockpile and check issue of compulsory licence against patented and otherwise prohibitively expensive vaccines in public health emergencies. The Committee finds that the Intellectual Property Rights (IPR) mechanism has been well grounded in the country and there is nothing in the provisions of the Indian Patents Act which contravenes the TRIPS framework. **The Committee recommends that the Government optimally use the flexibilities and safeguards under the TRIPS and the Indian Patents Act**

**and ensure that none of flexibilities and safeguards entailed in our Act is watered down in any case for any country. It emphasises that no medicine should be kept out of reach of the common man because it is exorbitantly priced to suit a pharma company enjoying its patent. The Committee insists that safeguards like CL be used to tackle such problem at the opportune time. We should not lose sight of the fact that access and affordability of medicines is integral to the fundamental right to life enshrined in our Constitution. Any policy that contradicts the basic fundamental rights of our citizens must be discarded.**

4.10 **The Committee also sincerely believes that the Competition Commission of India (CCI) must be made to play a more active role to ensure that the behavior of the pharma MNCs as well as the local pharma companies does not in any manner affect the availability and affordability of medicines to people at large.** The powers enjoined to the CCI to look at predatory pricing and unfair market practice on an ongoing basis is crucial in the given situation.

4.11 During the examination of the subject, the Committee found no coordinated approach in the government space of address critical issues affecting public health especially in respect of drugs and medicines. While drug-making is being looked after by Department of Pharmaceuticals; the drugs approval is under Department of Health and Family Welfare. Drug availability is to be ensured by Department of Pharmaceuticals, while drugs requirement is to be monitored by Department of Health and Family Welfare. Similarly, essential medicines are to be identified by

Department of Health and Family Welfare, its pricing is to be looked after by the Department of Pharmaceuticals. **The Committee, on occasions, found the two Departments at different wavelengths on issues of public health. In this backdrop, the Committee is of the considered opinion that since medicines/drugs are an integral aspect of public health structure, the Department of Pharmaceuticals may be subsumed within Ministry of Health and Family Welfare for effective policy formulation and monitoring of pharma sector in larger public interest.**

1. **The Committee finds this argument naive and desires that the government should stop behaving like an ostrich but instead take cognizance of the ground reality. Absence of such a mechanism is a handicap for the government while formulating policies for the sector. It is, therefore, high time that suitable mechanism be established to keep track of the nature of Foreign Direct Investments (brownfield and Greenfield investments) coming in the country. The Committee calls upon the Department to provide forth with the segregated data on greenfield and brownfield foreign direct investments made in the pharma sector.** (Para 2.3)

2. **The Committee finds this argument too simplistic. If the domestic companies mentioned above could start from scratch and become lucrative then there is no reason as to why a foreign pharma company cannot come and similarly do business. Moreover, their huge business experience and R&D base will always be handy to equip them for successfully competing in the shortest possible time.** (Para 2.24)

3. **The Committee wonders as to how MNCs are going to recover such huge costs. One possible way of doing so is to either concentrate more on manufacture and marketing of costly branded products or increase the prices of generic brands or it may resort to both the alternatives. In doing so, the pharma MNCs are likely to use the marketing and distribution network of Indian generic companies to push their costly patented/branded medicines and displace popular generic brands of the acquired company from the market.** (Para 2.25)

4. **The Committee is concerned about the shift of ownership of generic companies to the hands of MNCs that result in the change of the business model and the marketing strategy. In the case of acquisition, the acquired entity's business model is synchronised with the business model of the parent company whereby the acquired entity is not allowed to use flexibilities such as patent opposition or compulsory license to introduce new generic medicines. The withdrawal of all patent challenges by Ranbaxy on Pfizer's blockbuster medicine Lipitor filed in more than eight countries immediately after its acquisition by Daiichi-Sankyo is a case study by itself.** (Para 2.26)

5. **The Committee is dismayed by this argument of the DEA that very high valuation is basically a premium to check competition from the promoters of the acquired company in future. This, coupled with the**

**broad submission of DEA that the MNCs that have taken over Indian Pharma companies at substantial higher valuation have to recoup their investments and earn the maximum profits, hide the real intention of the pharma MNCs' high profile acquisition of big domestic pharma companies. The Committee recommends that the Department pierce the veil, take cognizance of the real threat, and take appropriate measures to ensure drugs security of the country.** (Para 2.28)

6. **The Committee is of the view that when a foreign company takes over a domestic company, immediate access of generics is available to that foreign company. The cost difference between some of the medicines that we produce here as 'generic' and what they produce there as 'branded' is sometimes as high as 80 to 85 times. This results in a win-win situation for every player, except us. When a foreign company acquires our domestic company, it exports our generics there and makes a huge profit. But if the same generic is sold at the higher price in India, the Indian public stands to lose and this is an area of concern. The Committee is of the strong opinion that any such attempt to sell generics at higher cost must be completely thwarted and the Government must establish a vigil on any such misdemeanour.** (Para 2.29)

7. **The Committee is deeply concerned over the spate of mergers/acquisitions/takeover of domestic pharma companies. It seems that the old hackneyed route for monopolists to buy out competition in order to prevent the emergence of low price market is in full play. The Committee is unhappy over these developments since the real danger of the 100 per cent FDI and the selling/takeover of Indian companies is the decimation of competition as well as capabilities.** (Para 2.30)

8. **The Committee shares the concern that serial acquisitions of the Indian generic companies by the MNCs will have significant impact on the competition, price level and availability. It could incapacitate the domestic industry and slow down new investments and employment generation by the domestic companies. All these in turn could adversely impact the availability and access to medicines at affordable prices. A few more takeovers of this kind may destroy the benefits arising out of India's generics revolution. This may even be a good strategy for the 'innovators' to 'silence' the generics frontrunners, thereby, retaining their innovation foundations while acquiring huge generic potential.** (Para 2.31)

9. **The Committee is of the view that the Department of Pharmaceuticals should be more proactive about the conduct and dealings of**

**pharmaceuticals companies in the country. This would enable it to prepare appropriate policy measures balancing the growth of pharmaceutical industry in the country as well as ensuring due discharge of social responsibility by the pharmaceutical industry towards public health.** (Para 2.33)

10. **It can be deduced from the figures that the FDI inflow into Research & Development of the Pharma Industry has been totally unsatisfactory. The Committee expresses its dissatisfaction that despite the profusion of FDI into the pharma industry in general, R & D in pharma has not got any significant benefit in particular. This trend is indicative of the fact that FDI is primarily being used to strengthen the business network of pharma MNCs and in keeping the domestic pharma companies in a subservient position without adding anything positive to the Indian health scenario. It is high time the Government took concrete steps to attract and ensure substantial amount of investments into R&D sector of the pharma Industry with special thrust on tropical diseases.** (Para 2.36)

11. **The Committee finds that acquisitions/collaboration of local companies has unfortunately forced R&D priorities to be increasingly set in tune with global trends neglecting R&D on 'tropical diseases' and also capability development of NCEs in this process.** (Para 2.38)

12. **The Committee is of the view that such collaboration is being valued more for the patients India can provide as guinea pigs for clinical research rather than for competencies. The Committee expresses its displeasure over such alliances of convenience. The Committee also condemns these unethical practices being pushed by pharma MNCs. Needless to mention such a situation has arisen owing to the absence of a strong regulatory framework. The Committee recommends that the Government frame guidelines for safe clinical trials and ensure its strict implementation. It hopes that the government will take appropriate measures to address the concerns regarding clinical trials, while not losing sight of the need to develop the competency of our pharma units to undertake clinical research for development of new drugs.** (Para 2.40)

13. **The Committee desires that world class infrastructure and facilities as well as adequate funding be made available to facilitate domestic companies in developing capacities for trials and testing.** (Para 2.41)

14. **The Committee feels that effective technology transfer is critical to success in the pharmaceutical industry. It is therefore imperative that the Government takes effective measures to promote development of technological capabilities in our pharma units. The various**

**collaboration models with pharma MNCs have certainly helped some of the domestic units improve their production capabilities by enforcing Good Manufacturing Practices but these business models have no significant impact on the technological capabilities of the local pharma firms.** (Para 2.42)

15. **The Committee is convinced that FDI has failed to bring about any real change in the existing pharma R&D environment as domestic pharma companies are still to gain the competence and capacity to achieve cutting-edge drug innovation by carrying a new compound through all stages of research up to marketing. After all these years of FDI in drugs and pharmaceuticals sector, India is still weak in laboratory stage drug discovery. As per a study, during the period 1999-2009, out of a total 166 disease type-wise R&D activities being conducted in India only 9 were undertaken for the neglected diseases (Type III), 10 for Type II diseases and the rest catered to Type I diseases which are pre-dominantly life-style diseases having a huge market in the western hemisphere. Similarly, during the period 2007-09, out of a total 186 clinical trials of type-wise diseases, only 5 Type III diseases were under clinical research whereas 175 Type I diseases were under clinical safety trials. The Committee is anguished over the pattern of research that has emerged on account of collaboration between foreign pharma companies and the domestic pharma companies which serves western markets rather than the needs of the local population.** (Para 2.43)

16. **The Committee notes that lack of public funding is a serious issue hindering the R&D efforts of the industry. Timely and adequate public funding is paramount to discovery of medicines which should be made available at cheaper costs. Pharmaceutical research is not only an expensive venture but also a risky one. The rate of failure is relatively high. The risk averting instinct of our country's R&D professionals needs to be addressed.** (Para 2.44)

17. **The Committee desires that adequate public funding must be earmarked for R&D in the pharma Sector so that technological capability is created to make us capable to discover new molecules and become self sufficient with regard to API / intermediates. The focus of R & D should be on tropical diseases and its cures as well as on improvement of the quality of the generics produced by us.** (Para 2.45)

18. **The Committee is of the view that FDI flow into brown field projects has not added fresh capacity in terms of production, distribution network or asset creation to the desired level. As a result, significant strides have not been made in creating fresh jobs and transfer of**

**technology. The Committee desires that the Department concerned must take desired steps to come up with optimal policy formulation in this regard.** (Para 2.47)

19. **The Committee fears that these MNCs can change or tweak the product mix and can go from producing generics into branded or even more expensive patented medicines. Its direct impact will be on the availability of the cheapest priced generics for Indian population which may decrease substantially. There is also the fear that a foreign company may not easily agree to compulsory licensing which will not be the case in an Indian company. Once a foreign company takes over an Indian company, it gets the marketing network of the major Indian companies and, through that market network, it changes the product mix and pushes the products which are more expensive and there is no provision to stop an MNC from changing the product mix. Internationally, because of its huge network and access to other markets, it can block our smaller domestic companies from establishing their presence in the global market.** (Para 3.1)

20. **The Committee is of the view that though the prices may not have increased significantly now but there is a threat that once our domestic capacity is crushed under the weight of the dominant force of multinational pharma companies, the supply of low priced medicines to the people will get circumvented. The Committee cautions the Government to remain vigilant and recommends establishing mechanisms to prevent increase in prices of medicines.** (Para 3.2)

21. **The Committee is of the opinion that foreign investments *per se* are not bad. The issue was not about promoting FDI for takeover/requisitions of domestic pharma units but to promote more investments into the pharma industry so that there is greater research, adequate availability of medicines and more competition which will ensure affordable and accessible medicines. It is important to ensure the presence of sufficient number of companies so that there is competition which will keep a check on the prices of drugs. The decimation of the strength of local pharma companies runs contrary to the above desired position since there would be few or no Indian companies left having necessary wherewithal to manufacture generics once a drug goes off-patent or comply with a Compulsory License (CL). The permission to allow acquisition/merger would finally leave generics production in the hands of pharma MNCs who would never like to promote them in comparison to their branded medicines. The Committee expresses its dissatisfaction with such a development.** (Para 3.3)

22. **The Committee is of the view that this is an example of unfair trade practices adopted by pharma MNCs where they first influence generic manufacturers to go slow and then buy the generic drugs competition to completely stop their movement in the drugs market. In this process, it is the common man who loses his basic right to affordable medicines.** (Para 3.4)

23. **The Committee has been informed of several irregularities in the distribution and retail sale of medicines. It emphasizes the need for the Government to step in and revamp the distribution system so that people have access to good quality medicines. The Committee had occasion to study the functioning of the Tamil Nadu Medical Services Corporation (TNMSC) and the Rajasthan Medical Services Corporation (RMSC) and it found that these agencies have efficiently procured generic medicines at prices 50 to 60 times less than the retail prices of market leaders. The Committee recommends that the Government examine the Tamil Nadu/Rajasthan model and suggest a model scheme for providing affordable medicines to one and all in the country.** (Para 3.6)

24. **The Committee recommends the Government take all measures to ensure that essential medicines are affordable to the common man. It should come up with a viable method of price fixation which primarily serves the above purpose. This price control mechanism should incorporate the instrumentality of fixing the launch price of the drug at the time of its introduction, rather than feel helpless in adjudging the launch price on objective criteria. The Committee feels that cost-based pricing model may be considered for the purpose.** (Para 3.7)

25. **The Committee emphasizes the need for widespread promotion of quality generic medicines in the country. Since generics are as effective as branded generics and are cheaper, the Government must take all measures to protect the domestic generics industry. This is more important in view of the fact that a large section of our population is deprived of medicines on account of their high cost. It goes without saying that unbranded generic medicine is the only hope for the teeming millions in our country and also other parts of the globe. Any policy that adversely affects, howsoever remotely, the generics capacity of our country must be discarded. The Committee believes that we must only promote consumption of unbranded generic medicine in the country. The Government has put the onus on Medical Council of India (MCI) for this task which is not sufficient. The Committee recommends that Government bring in legislation to make it legally binding on all the doctors to prescribe generic drugs in their prescriptions and/or clearly prescribe generic equivalents of branded medicines. This will not only**

**give a spurt to our domestic pharma industry consisting of predominantly small and medium units but also ensure access to medicines to all in the real sense. Documentaries/Visual advertisements/short films should also be made by Films Divisions to bring awareness about generic medicines in rural areas of the country.** (Para 3.8)

26. **The Committee shares the concern of the Department. The Committee finds that pharma MNCs are extremely opaque about revealing the cost of a patented drug but are also more often than not, trying to hold on to patents even after the expiry of the drug by tweaking the composition of the drug, a process commonly known as evergreening. The recent Supreme Court judgment denying patent right to Novartis, a multinational pharmaceutical company, for continuing patent rights over Glivec, a potent anti-cancer drug is a pointer in this direction.** (Para 3.9)

27. **The Committee desires that more such drugs must be identified on continuous basis and their prices be reduced suitably by utilizing the various instruments like compulsory licence, etc. and other safeguards envisaged under TRIPS and our Patent Act. The Committee is of the view that the availability of patented drug to the needy is more important than the interest of the patent holder.** (Para 3.11)

28. **The Committee is of the considered view that the Government must take up the TRIPS agreement afresh at an appropriate forum and collectively work with world governments to ensure that flexibility in periodicity of exclusive manufacturing right to a patentee company is introduced in the patent regime depending upon the amount of expenditure incurred by the patentee as well as the extent of its contribution in the R&D.** (Para 3.13)

29. **The Committee takes serious note of this matter and desires that such benefits should ultimately serve the interest of the public rather than benefiting MNCs. The Committee recommends the Department draft some mechanism whereby the benefits availed and the cost of the brand value acquired owing to such governmental assistance may be recovered from these pharma companies on their divesting of the shares for money.** (Para 3.14)

30. **The Committee feels that these PSUs served the public in terms of availability, accessibility and affordability of medicines in the Indian context. They need to be revived, re-strengthened and made dynamic and healthy so that generic medicines and vaccines are produced in larger quantities and made available to the masses at reasonable prices.**

**The Committee also feels there is an urgent need to investigate the reasons behind the poor performance and near-closure of PSUs so as to address the issues and to ensure that resources are utilized in the appropriate manner. The Committee observes that the absence of a robust public sector health service has impeded the universalisation of healthcare. In a situation when the private sector fails to step in and address the health needs of this country, the public sector would be a credible system to cater our growing health needs. A robust public sector would ensure self-sufficiency and shield the pharma sector from adverse effects of market dynamics and investment policies.** (Para 3.16)

31. **The Committee notes that the adverse effect of takeover/acquisition is starting to show as the export performance in dollar terms during 2012-13 has not been satisfactory as compared to the past two years. The targeted figure of US $ 24 billion exports would be difficult to achieve by the projected time-line of March, 2014. The Committee desires that appropriate actions are taken by the Government to arrest the deteriorating performance of our pharma industry on export front.** (Para 4.2)

32. **The Committee also notes the danger arising out of FDI in brown field pharma projects to the entire health and IPR framework of our country in terms of access and affordability of medicines, domination and elbowing out of our pharmaceutical industry comprising of predominantly small and medium pharma units, undue demand and pressure on TRIPS arrangements, etc. The Committee is, therefore, of the considered opinion that the Government must impose a blanket ban on any FDI in brown field pharma projects. It strongly recommends that the Department take all measures to stop any further takeover/acquisition of domestic pharma units. This necessity becomes more telling in view of the fact that the pharmaceutical industry is not like any other industry/business. It is one sector of the economy which has to be dictated by public good rather than foreign investments, profit and revenue.** (Para 4.4)

33. **The Committee feels that FDI in brown field pharma sector has encroached upon our generics base and adversely affected our pharma industry.** (Para 4.5)

34. **The Committee feels that introduction of FIPB approval mechanism is a feeble attempt which would not be able to measure upto the challenges posed by this route. The Committee is also of the view that restricting the inflow of FDI however can only have a limited impact. It sincerely believes that to ensure availability of essential drugs to the common**

**man, all forms of production, pricing and distribution of pharmaceuticals have to be effectively monitored by the Department of Health and Family Welfare themselves or through regulations or through an independent regulator. It is always convenient to monitor through a single agency than to allow multiple regulators working in different directions with different mandates without much accountability.** (Para 4.6)

35. **The Committee, nevertheless, agrees with the present FDI policy on green field pharma projects permitting upto 100 per cent under automatic route. The Committee desires that the Department undertake consultations with all stakeholders to create favourable conditions to promote green field investments in pharma sector. It is also of the view that FDI in green field pharma projects may be automatic but subject to some conditions. It must be ensured that the failure to comply with provisions should attract penalty including cancellation of registration. Foreign investors must also bring in new technology for local production of Active Pharmaceutical Ingredient (API) manufacturing from basic stage. It is important to create API capabilities since we heavily depend on other countries, especially, China for our API requirement and our medical security is at stake. Sectoral regulations must ensure that the foreign companies set up indigenous production of patented medicines which are totally imported today.** (Para 4.7)

36. **The Committee recommends that the concerns/ recommendations/ observations made by it in the above paras may be spelt out as policy parameters and placed in the public domain so that the investors are fully aware of the compliance requirements. Any uncertainty of outcome or piece-meal approach to approvals may cause investor anxiety. Public health concerns should be addressed through pharma-related supporting institutions, laws of the land, structures and regulations.** (Para 4.8)

37. **The Committee recommends that the Government optimally use the flexibilities and safeguards under the TRIPS and the Indian Patents Act and ensure that none of flexibilities and safeguards entailed in our Act is watered down in any case for any country. It emphasises that no medicine should be kept out of reach of the common man because it is exorbitantly priced to suit a pharma company enjoying its patent. The Committee insists that safeguards like CL be used to tackle such problem at the opportune time. We should not lose sight of the fact that access and affordability of medicines is integral to the fundamental right to life enshrined in our Constitution. Any policy that contradicts**

**the basic fundamental rights of our citizens must be discarded.** (Para 4.9)

38. **The Committee also sincerely believes that the Competition Commission of India (CCI) must be made to play a more active role to ensure that the behavior of the pharma MNCs as well as the local pharma companies does not in any manner affect the availability and affordability of medicines to people at large.** (Para 4.10)

39. **The Committee, on occasions, found the two Departments at different wavelengths on issues of public health. In this backdrop, the Committee is of the considered opinion that since medicines/drugs are an integral aspect of public health structure, the Department of Pharmaceuticals may be subsumed within Ministry of Health and Family Welfare for effective policy formulation and monitoring of pharma sector in larger public interest.** (Para 4.11)

# ANNEXURE

**ANNEXURE - I**

## DETAIL OF MEMORANDA RECEIVED

| SL. NO. | NAME OF INDIVIDUAL / ORGANISATION | ADDRESS | CONTACT DETAIL | | |
|---|---|---|---|---|---|
| | | | CELL PHONE NO. | LANDLINE | EMAIL |
| 1. | Shri K.Ravikumar | Ajaya Bhawanam, Changankulangara, Oachira, P.O., Kollam, Kerala-690526 | ----- | ----- | ----- |
| 2. | Shri R.K. Gupta, Scientific Officer (Retd) | 701, Sterling Apartment, Lala Jamanadas Gupta Marg, Deonar, Mumbai | ----- | ----- | ----- |
| 3. | Shri Janakiram Rao, Sr. Superintendent (Refined), Central Excise/Customs | D-304, Vrindavan Haware, Sector-9, Khanda Colony, New Pannel-410206 | ----- | ----- | ----- |
| 4. | Dr. Arun Malhotra, Ph.d. Professor & Head | All India Institute of Medical Science, Department of Nuclear Medicine, Ansari Nagar, New Delhi-110029 | ----- | 26589876, 26593210 (O) 26589651, 26594539 (R) 26588531 (Fax) | drmalhotraarun@gmail.com |
| 5. | Shri Kapil Kumar Sharma | Near Maharaja Public School, Ganga Dham, Bassi, Jaipur, Rajasthan | ----- | ----- | ----- |
| 6. | Ms. Rajula Barot, President | Mahila Adhikar Sangh, F-9/10, Baijanwala Complex, Opposite SMC Zone Office, Tadwadi, Rander Road, Surat-395005 | 09825968156, 09173737371, 09898148712 | ----- | abpandya1956@hotmail.com |
| 7. | Shri D.M.Chamlwar | Vaishali Bunglow, Topenagar, Amrawati (Maharashtra) | 09423032259 | ----- | dmchamalwar@gmail.com |
| 8. | Shri H.K. Pradhan | Meghabas, Bidhanpally, P.O. Kadamtala, Siliguri, W.Bengal, Pin-734011 | 09800490136 | 0353-2580506 | meghabas@gmail.com |
| 9. | Shri Avnish Pandya | ----- | ----- | ----- | abpandya1956@hotmail.com |
| 10. | Shri Dhananjay Chamalwar | Maharashtra, Amrawati | 09423032259 | ----- | dmchamalwar@gmail.com |

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|---|---|---|---|---|---|
| 11. | Shri G.Srinivas | ----- | ----- | ----- | Saisrini9@gmail.com |
| 12. | Prof (Dr.) Brijesh Kumar Tiwari, Principal | NKBR, College of Pharmacy and Research Centre, Meerut. | ----- | ----- | transbrijesh@gmail.com |
| 13. | Shri Tapan Ray, Director General | Organization of Pharmaceutical Producers of India, Peninsula Corporate Park, Peninsula Chambers, Gr. Floor, Ganpatrao Kadam Marg, Lower Parel, Mumbai-400013. | ----- | 22-24918123, 24912486, 66627007 Fax: 24915168 | tapan.ray@indiaoppi.com Website: www.indiaoppi.com |
| 14. | Shri R.P. Yajurvedi (Rao) | Society for Awareness of Civil Rights, J-220, Ansa Industrial Estate, Saki Vihar Road, Saki Naka, Mumbai-400072 | ----- | ----- | civilrights2009@gmail.com |
| 15. | Shri Sayish. M | Manakkal House, Post-Guruvayur, Appan College, Pokkunnu, Kozhikode, Pin-673014 | ----- | ----- | ----- |
| 16. | Shri S. Srinivasan, Managing Trustee | LOCOST, Baroda | ----- | ----- | sahajbrc@gmail.com |

# MINUTES

## *XVIII
## EIGHTEENTH MEETING

The Department Related Parliamentary Standing Committee on Commerce met at 3.00 P.M. on Monday, the 20th June, 2011 in Committee Room 'B', Ground Floor, Parliament House Annexe, New Delhi.

**PRESENT**

**MEMBERS**

1. Dr. E.M. Sudarsana Natchiappan (In the Chair)

**RAJYA SABHA**

2. Prof. P.J. Kurien
3. Shri V. Hanumantha Rao
4. Shri K.N. Balagopal
5. Shri Ishwarlal Shankarlal Jain
6. Shri Prem Chand Gupta

**LOK SABHA**

7. Shri G.S. Basavaraj
8. Shri K.P. Dhanapalan
9. Shri Shivarama Gouda
10. Prof. Sk. Saidul Haque
11. Shri O. S. Manian
12. Shri Deoraj Singh Patel
13. Shri Modugula Venugopala Reddy
14. Shri M.I. Shanavas
15. Shri Rajaiah Siricilla
16. Shri Thol Thirumaavalavan

**SECRETARIAT**

Smt. Sharada Subramaniam, Joint Secretary
Dr. (Smt.) Subhashree Panigrahi, Joint Director
Smt. Indira Chaturvedi Vaidya, Assistant Director
Shri R.K. Sharma, Committee Officer

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* 1st to 18th Meetings of the Committee pertain to other matters.

**WITNESSES**

**REPRESENTATIVES OF DEPARTMENT OF INDUSTRIAL POLICY AND PROMOTION, MINISTRY OF COMMERCE & INDUSTRY**

Shri Rajinder Pal Singh, Secretary
Smt. Anjali Prasad, Joint Secretary
Shri D.V. Prasad, Joint Secretary
Shri Deepak Narain, Director
Smt. Chandani Raina, Director
Shri S. Natarajan, Under Secretary

2. In the absence of the Chairman, Dr. E.M. Sudarsana Natchiappan chaired the meeting of the Committee.

3. The Chairman welcomed the Members and informed that the Committee in its meeting held on 3rd May, 2011 decided to take up the subject of 'Foreign and Domestic Investment in Pharma Sector' for detailed study. The Secretary, Department of Industrial Policy & Promotion (DIPP), Ministry of Commerce & Industry has been invited to give presentation on the subject. In this regard, he also drew the attention of the Members to Parliamentary Bulletin Part II dated 17th June, 2011, regarding reiteration of the Rule 294 (i) (for declaration of interests) of the Rules of Procedure and Conduct of Business in the Council of States by Chairman of the Parliamentary Committees. [The witnesses were then called in]

4. The Secretary, DIPP stated that India is known as the pharmacy of the world for low-cost drugs, and it attracts third world countries and the developing countries, which cannot afford high cost patented medicines, for generic drugs. India has been able to build and produce generic drugs over a period of time because it joined the product based patent regime in 2005. He stated that there is a possibility of a large number of patented drugs coming out of patent regime into what is called the 'White Space'. This further posed the fear of acquisition of generic drugs producing companies by MNCs. He informed that presently there is

100 per cent FDI through automatic route and there is no need of any license for this sector. This resulted in large amount of FDI coming into the existing companies which defeated the very purpose of the FDI because the purpose of FDI is to spur manufacturing of drugs in India. He, therefore, stated that we should continue to permit investments in the Green field on the automatic route but acquisitions or investments in the Brown Field companies should be through Government's route which meant that the company has to apply to the Foreign Investment Promotion Board (FIPB) who can frame its guidelines and rules as to where to give permission and where to reject the request of the companies. He also informed the Committee that a suggestion in this regard was conveyed to all the concerned departments viz. Department of Health, Department of Economic Affairs and Department of Pharmaceuticals for their comments and as soon as the views of these Departments are received, orders will be issued.

5. The Secretary also stated that for sectoral policies, the DIPP generally allows the concerned Departments to take a decision. However, the DIPP's view is to encourage competition, i.e., to encourage more and more companies to produce generic drugs. He was of the view that in order to increase the production in the pharma sector there is a need to revamp the public sector units so that drugs remain available at affordable prices not only to Indian consumers but even to the consumers in third world countries.

6. After the presentation, the Members of the Committee raised the following issues: -

(i) Price control mechanism under the Act;

(ii) Limiting of the FDI;

(iii) FIPB route for Brown field projects;

(iv) Free entry of MNCs to acquire brown field companies;

(v) Growth of Indian pharmaceutical industry after the FDI was liberalised;

(vi) Feasibility to change Indian Patents Act to protect domestic companies;

(vii) Details of study on regulation of the inflow of foreign money under the pharma policy;

(viii) New entrants in the pharma field and the role of pharma policy;

(ix) Statutory institutions to address the pharma policy; and

(x) Study on comparative market for allowing FDI in pharma Sector.

7. The witnesses clarified some of the queries. The Chairman requested the witnesses to send detailed written replies to the queries, not answered orally.

8. A verbatim record of the proceedings of the meeting was kept.

9. The Committee then adjourned at 4.15 p.m. to meet again at 1.00 p.m. on 27th June, 2011.

## II
## SECOND MEETING

The Department Related Parliamentary Standing Committee on Commerce met at 11.00 A.M. on Thursday, the 29th September, 2011 in Committee Room 'A', Ground Floor, Parliament House Annexe, New Delhi.

**PRESENT**

**MEMBERS**

1. Shri Shanta Kumar — *Chairman*

**RAJYA SABHA**

2. Dr. E.M. Sudarsana Natchiappan
3. Shri Jai Prakash
4. Shri Ishwarlal Shankarlal Jain
5. Shri Prem Chand Gupta

**LOK SABHA**

6. Shri G.S. Basavaraj
7. Shri C. M. Chang
8. Prof. Sk. Saidul Haque
9. Shri Dilip Singh Judev
10. Shri Nalin Kumar Kateel
11. Shri M.I. Shanavas
12. Shri Jagdish Sharma
13. Shri Rajaiah Siricilla
14. Shri K. Sudhakaran
15. Shri Dharmendra Yadav

**SECRETARIAT**

Smt. Sharada Subramaniam, Joint Secretary
Dr. (Smt.) Subhashree Panigrahi, Joint Director
Shri Amit Kumar, Assistant Director
Shri Rajesh Kumar Sharma, Committee Officer

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* 1st Meeting of the Committee pertains to other matters.

**WITNESSES**

**REPRESENTATIVES OF PLANNING COMMISSION**

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**REPRESENTATIVES OF DEPARTMENT OF HEALTH, MINISTRY OF HEALTH & FAMILY WELFARE**

Shri Anil Kumar, Secretary
Dr. R.K. Srivastava, DGHS
Shri L.C. Goyal, AS & DG
Dr. Surinder Singh, DCG (I)
Shri Sanjay Prasad, Director
Shri Sudhir Kumar, Under Secretary

**ORAL EVIDENCE OF SENIOR CONSULTANT, PLANNING COMMISSION**

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**ORAL EVIDENCE OF SECRETARY, DEPARTMENT OF HEALTH, MINISTRY OF HEALTHE AND FAMILY WELFARE**

11. The Chairman again welcomed the Members on reassembly for the meeting on the subject 'FDI in Pharmaceutical Sector'. The Chairman observed that the basic policy guiding the FDI inflow in the country has been creation of manufacturing capabilities, introduction of new technologies and employment generation. However, FDI in pharmaceutical sector has, to a large extent, been used as a mask for acquiring equities of local pharmaceutical companies by the MNCs. This development has inherent danger of circumventing supply of cheap

medicines to the people and can be used for earning high profits without capacity building and employment generation.

12. The Secretary submitted that there was a need to exercise certain degree of regulatory check over companies in the pharmaceutical sector. He observed that though India is a strong country as far as production is concerned, but the country has not yet reached a position to control the international market dominantly since it has a share of only two per cent in terms of international market value. The country still has a long way to go since the market is currently dominated by North America, Europe, and Japan.

13. It was informed that our total domestic production is worth 20 billion US dollars or at today's exchange rate roughly Rs. one lakh crore. Out of one lakh crore rupees, Rs.58,000 crore is the value of the domestic market; and we have got a strong export presence of roughly Rs.42,000 crore in 200 countries. Ninety-five per cent of our domestic requirement is met from our own domestic production.

14. The Secretary submitted that in the last few years, the position on account of FDI in pharmaceutical sector had not been very comfortable. In fact, it was alarming, to put it very mildly. It was highlighted that since 2006, there have been seven takeovers. These companies are: Matrix Lab, Dabur Pharma, Ranbaxy Labs, Shanta Biotech, Orchid Chemicals and Piramal Healthcare. All these companies have been taken over at higher valuations than their actual valuations which are a cause of concern. The Secretary while giving a brief overview of the nature of markets in the developed countries pointed out that developed countries adopted a different pattern of healthcare development as a result of which the cost of their healthcare is extremely high and hence these countries are looking to reduce their healthcare budgets. The way out was to replace their branded/patented drugs with cheaper generics. Since our country is one of the strongest producers of generics in the world, there have been brown field acquisitions. It was pointed out that when a foreign company takes over a domestic company, immediate access of

generics was provided to that foreign company. The cost difference between some of the medicines that we produce here as 'generic' and what they produce there as 'branded' was as high as 81 times. This results in a win-win situation for everyone, except us. Because when a foreign company acquires our domestic company, it exports our generics there and make a huge profit. But if it tries to sell it at that high price in India we are the ones who lose and this was an area of concern.

15. The Secretary then gave an analysis of the effects of such takeovers. He informed that twenty-eight per cent of the markets were already controlled by the pharma multinational companies, which was a big thing since even five per cent share can impact the availability, price, etc. If another top three Indian companies are acquired by the MNCs, their share would rise to 41 per cent and on acquisition of next rung of eight companies, their share will go over 55 per cent which was very alarming. It was pointed out that in the last five years, the market share of pharma MNCs has grown from 15 to 25 per cent. There is the fear that these MNCs can change the product mix and there can be no control over changing the product mix. From producing generics, it can go into branded or even more expensive patented ones. Its direct impact will be on the availability of the cheapest price generic for Indian population. Its availability may decrease substantially. There is also the fear that a foreign company may not easily agree to compulsory licensing which will not be the case in Indian company. Once a foreign company takes over an Indian company, it gets the marketing network of the major Indian companies and, through that market network, it changes the product mix and pushes the products which are more expensive and there is no provision to stop that. Internationally, because of its huge network and access to other markets, it can block our smaller domestic companies from establishing their presence in the global market. It was submitted that the Indian pharma market is very fragmented and there are very few companies which are operating at the top level. It is the big companies which could be the major players but these big

companies were being taken over. Our smaller companies with their little resources will never be able to establish their potential in the international market. Thus, there will be no challenge for these pharma MNCs and this development has inherent danger.

16. It was pointed out that the FDI has neither led to job creation nor led to creation of gross fixed assets. In the last five years the gross fixed assets was worth of Rs.54,000 crores. The MNCs which have taken over these companies have added mere Rs.3000 crores. Research and Development could not be taken up at desired level. The FDI has merely resulted in change in ownership with no addition to manufacturing capacity.

17. It was further stated that India though is a signatory to TRIPS Agreement yet there are pressures that it should go beyond TRIPS Agreement, particularly in the healthcare sector. The Secretary argued that with the presence of huge companies operating in our domestic market and exporting the product from India and feeding their own domestic market, they would certainly acquire a very strong voice putting the country under pressure on issues relating to TRIPS Agreement which may not be in its interest.

18. It was mentioned that the stated policy of the Government was to provide healthcare to our population at all costs. Sixty eight per cent of the people are still to be fully covered. This alarming situation has to be overcome in shortest possible time. It was informed that the health budget is going to see a substantial increase in the coming Twelfth Plan. New health programmes like National Urban Health Mission were being planned under which the entire urban sector was to be covered. On account of existing programmes like NRHM and other proposed schemes, the requirement of medicines was going to increase tremendously. It was submitted that if the price of medicines goes up to an extent so that it dry out the finances proposed for other components of health plan, then the consequences would be fateful and unaffordable for the country.

19. The Secretary pointed that out of 67 FDI investments; only one has been in green field while the remaining was brown field. He stated that the Department of Health didn't want any cap on 100 per cent FDI in green field projects. However, in cases of brown field acquisitions where the ownership was being transferred, it was submitted that some sort of regulatory mechanism be put in place at the time of giving permission so that issues of health care were adequately addressed.

20. The Secretary, then, briefed the Committee about drugs price control mechanism. It was informed that drugs control come under the Concurrent List of the Constitution. The Central Government unlike the State Governments have limited licensing powers which it exercise through the Drug Controller General of India in a very limited number of medicines and for new drugs. It was submitted that through the Central Drug Standard Control Organization which is headed by Drug Controller General of India , the Government tries to regulate the standards of laboratories. However, in the past the structures on regulation of control of laboratories for testing did not keep pace with the growth of industry. Now concerted efforts were being made in last couple of years to improve the situation through appointment of more drug inspectors, strengthening of laboratories at the State level, etc.

21. It was informed that the industry growth and the drug price control order were the responsibility of the Department of Pharmaceuticals. The Secretary stated that the Department of Health has prepared a National List of Essential Medicines (NLEM) revised in 2011. There are 348 drugs under this list. He requested that the Department of Pharmaceuticals must be impressed upon to include these 348 drugs under the drug price control order administered by National Pharmaceutical Pricing Authority at the earliest.

22. After the submissions, Members raised their concerns on the following issues and also sought clarifications/suggestions on them:

(a) impact of FDI in Pharma Sector on the availability of cheap drugs;

(b) status of the promoter of domestic pharma companies who have sold their majority shares to pharma MNCs;

(c) find ways and means to check manufacture of spurious drugs in the country and to also check the increase in prices of medicine;

(d) reasons for the long delay in sanctioning the draft National Pharmaceutical Policy and including 348 medicines of the National Essential Medicine List, 2011 under Drug Price Control Order;

(e) mandate of Competition Commission of India to look into the problems arising out of brown field acquisition;

(f) problem of doctors prescribing costly drugs of pharma MNCs instead of prescribing generic drugs; and

(g) study regarding the cost of production of drugs and market price of drugs.

23. Secretary, Department of Health gave clarifications to the queries raised above. The Chairman requested to send written replies to the queries not responded. The witnesses, then, withdrew.

24. The Committee adjourned at 1.25 P.M.

## III
## THIRD MEETING

The Department Related Parliamentary Standing Committee on Commerce met at 3.00 P.M. on Wednesday, the 12th October, 2011 in Room No. '63', First Floor, Parliament House, New Delhi.

**PRESENT**

**MEMBERS**

1. Shri Shanta Kumar — *Chairman*

**RAJYA SABHA**

2. Dr. E.M. Sudarsana Natchiappan
3. Shri Jai Prakash
4. Shri K.N. Balagopal
5. Shri Ishwarlal Shankarlal Jain
6. Shri Prem Chand Gupta

**LOK SABHA**

7. Shri Kantilal Bhuria
8. Shri K.P. Dhanapalan
9. Prof. Sk. Saidul Haque
10. Shri M.I. Shanavas
11. Shri Jagdish Sharma
12. Shri Rajaiah Siricilla
13. Shri Dharmendra Yadav

**SECRETARIAT**

Smt. Sharada Subramaniam, Joint Secretary
Dr. (Smt.) Subhashree Panigrahi, Joint Director
Shri Amit Kumar, Assistant Director
Shri Rajesh Kumar Sharma, Committee Officer

**WITNESSES**

**REPRESENTATIVES OF PLANNING COMMISSION**

Shri Arun Maira, Member, Planning Commission
Dr. (Smt.) Renu S Parmar, Adviser, Planning Commission
Shri D. Banerjee, Jt. Adviser, Planning Commission
Shri Anurag Goel, Member, Competition Commission of India
Shri Parvin Purwar, Adviser, Competition Commission of India

**REPRESENTATIVES OF INDIAN PHARMACEUTICALS ALLIANCE**

Shri D.G. Shah, Secretary General

2. The Chairman welcomed the Members to the meeting of the Committee and informed them that Member (Industry), Planning Commission and the Secretary-General, Indian Pharmaceutical Alliance (IPA) had been invited to give their views on FDI in Pharmaceuticals Sector. He, then, drew the attention of the Members to the Direction of Hon'ble Chairman, Rajya Sabha regarding declaration by the Members of the Committee about the nature of personal or specific pecuniary interest, direct or indirect, in a matter being considered by the Committee before their participation in the debate on the matter.

**ORAL EVIDENCE OF MEMBER (INDUSTRY), PLANNING COMMISSION ON FDI IN PHARMACEUTICALS SECTOR**

3. The Chairman welcomed Member (Industry), Planning Commission and other officials to the meeting. He expressed the Committee's concern that FDI in pharma has been largely directed towards acquiring Indian pharma 'jewels'. He enquired about the motive behind overvalued mergers and acquisitions of domestic pharma companies and the rising cost of medical drugs for the general citizens of the country. He sought information regarding the issues arising out of unchecked FDI in brown field companies. The Chairman further sought information regarding the extent of problem arising out of overvalued FDI in brown field pharma companies and the efficacy of the

Competition Commission of India in regulating such FDI so as to protect the interests of the common man in India. He also wanted to know the reasons for close to zero FDI inflow in green field projects in the country.

4. Member (Industry) stated that as the Head of the High Level Committee, his aim has been to ensure that whatever happens in the industry should not be detrimental to the interest of the poor in terms of the availability of medicines or prices of medicines. He submitted that it was too early to tell the consequences of FDI in brown field projects and the consequential prices in the market. However, after examining the effect of FDI on prices of medicines on the basis of whatever little evidence the HLC had before it, it has been noticed that so far, prices of medicines have not gone up as a result of FDI. Nevertheless, the HLC has placed premium on being vigilant and has recommended establishing mechanisms to prevent undue increase in prices of medicines. It was mentioned that the safeguard mechanism proposed to be placed should also ensure that investment in this industry was not adversely affected since India has a large population which is inadequately served and whose needs were going to go up even further. We needed much more investment, both foreign and domestic, for the growth of our pharmaceuticals industry in the country.

5. Members, Planning Commission informed the Committee that there were two mechanisms available to us to monitor acquisitions, firstly, the old traditional mechanism of regulating through Foreign Investment Promotion Board (FIPB) whereby, we can administratively put caps or limitations on the inflow on FDI. Secondly, to regulate unhealthy competition generated by mergers and acquisitions through the Competition Commission of India. Member, Planning Commission emphasized that Competition Commission is a very strong comprehensive mechanism to ensure that acquisitions are monitored, controlled and permitted only if the consequences cause damage to the structure of the industry or to the prices thereafter.

6. He informed that Sections 5 and 6 of the Competition Act which apply to acquisitions and mergers were made operational by notification only this year. Upon notification of Sections 5 and 6 of the Act, all acquisitions whether cleared by FIPB or not, are required to be monitored by the Competition Commission. Highlighting the efficacy of the Competition Commission, he stated that their process was a time-based, transparent, and evidence based process whose decision was appealable so that justice was available to all parties. He further submitted that though the threshold size of acquisition which would attract scrutiny of the Competition Commission has been raised beyond what was prescribed in the Act, yet in view of the sensitive nature of pharmaceuticals industry, the HLC has recommended that every potential acquisition in pharma industry must get the prior clearance of the Competition Commission so as to ensure that there is no likelihood of increase in prices.

7. Member, Planning Commission then spelt out the reasons which have been constraining Greenfield investments in the country. He submitted that difficulty in land acquisition has been a restraint on expansion in the Greenfield investment. Other factors like requirement of multiple permissions/clearances like environmental clearance have a dampening effect upon investment in all industries including pharma. He informed the Committee that a new manufacturing policy was on the anvil, the implementation of which would attract more investments into Greenfield manufacture.

8. The Member, Planning Commission informed that though we are still short of entry into the big league of R&D, yet we are placed better than most of the countries in research and development. In fact, the present base of scientists and R&D abilities as well as well-equipped laboratories makes acquisition an attractive proposition in the country. The Member also underlined the need to improve our own regulatory mechanism for development of medicines in the country. Besides, he also informed that Department of Science and Biotechnology shall encourage

more development of medicines in the country both by Indian companies as well as by foreign companies during the Twelfth Five Year Plan.

9. The Member, Planning Commission stated that to ensure the end objective of access of medicines at the lowest possible price by all, a lot of work is required to be done on the other side of the chain. It is not on the acquisition side of the chain alone. The HLC was given the mandate to look into modalities to prevent damages that might accrue due to acquisitions and the HLC attempted to find solutions to such acquisitions. To act on the other side, we need to be much stronger on price controls and anti-consumer practices. In this scheme of things, the pharma Public Sector Companies have to play a very major role in three ways:

(i) invest into pharma innovations relevant to our country and not others;

(ii) use public distribution system effectively for providing medicines to poor people; and

(iii) engage in production of essential drugs.

10. Member, Planning Commission further stated that the future action of pharma MNCs is unclear but it is important to put in place all mechanisms to avoid any adverse impact on availability of cheap medicines. He submitted that the issue was not about promoting FDI but to promote more investments into the pharma industry so that there is greater availability of medicines and more competition which will ensure affordable and accessible medicines. It is important to ensure the presence of sufficient number of companies so that there is competition which will keep a check on the prices of drugs.

11. Advisor, Competition Commission of India explained the threshold criteria to the Committee. He stated that the Competition Act envisaged joint threshold but through a Notification of the Ministry the concept of target company (i.e., acquired enterprises) has been introduced whereby, any acquired enterprise which has a turnover of less than Rs. 750 crore and the assets worth less than Rs. 250 crore has been excluded from the purview of the CCI. Thus, any company which

fits into asset and turnover criteria will be reportable to CCI irrespective of the value of transaction.

12. Member, Planning Commission emphasized on the need to revamp the distribution system so that people have access to good quality medicines. He stated that anti-consumer behavior happens inside the distribution and retail part of the industry, regardless of whether it is a foreign company or Indian company. He informed that Sections 3 and 4 of the Competition Act enables the CCI to look at anti-competitive behavior as well as anti-consumer behavior in the market.

13. It was submitted that the HLC firmly believed that regardless of free market, price control of essential medicines must be retained and strengthened. He mentioned about the price control mechanism which is a safe guard to ensure that the price of drugs does not rise more than 10 percent in a year. Further, under the Compulsory Licencing mechanism we can also ensure the adequate availability of a drug at low price to people in the market. Member, Planning Commission further stated that necessary IT softwares may be developed to show the plain generic alternates of branded generics and put to good use by consumers. This would ensure that people are not exploited by the doctors if they prescribe expensive branded drugs.

14. After the submissions, Members raised their concerns on the following issues and also sought clarifications/suggestions on them:

(i) the impact of acquisitions of Indian companies by foreign companies and the extent of its detrimental effect on public health;

(ii) the nature of the Standing Advisory Committee that is expected to support Competition Commission of India as per the recommendations made in the Report of the HLC;

(iii) the value of the threshold limits fixed for screening acquisitions in pharma sector;

(iv) the reasons for dissent note of Department of Industrial Policy and Promotion indicating that FIPB rather than CCI is the appropriate authority to screen FDI investments in brownfield projects;

(v) efficacy of the proposal to put a blanket cap on profit margin of all the medicines across the board in view of the fact that the National Pharmaceutical Pricing Authority which determines the prices have themselves conveyed their helplessness in curtailing prices;

(vi) whether any study has been commissioned to examine the status in R&D, employment generation and skills management, post acquisition, in the country;

(vii) the source of funds of FDI for acquisitions and the quantum of money being remitted post profit by the pharma MNC after acquisitions of local companies;

(viii) the expected decrease in share of Indian companies in the total global market due to acquisitions;

(ix) efficacy of the proposal to impose controls on foreign pharmaceutical companies on exporting drugs and medicines so that essential medicines are available in the country;

(x) ways and means to increase the availability of generic drugs to people;

(xi) efficacy of Competition Commission of India to check difference in price of same medicine at different places and ways and means to fix maximum retail price of drugs;

(xii) status of revival of Indian Drugs and Pharmaceuticals Limited (IDPL) or establishment of similar public sector enterprises for production of medicines required by masses; and

(xiii) creation of a powerful National Pharmaceutical Authority through statutory means consisting of experts to look into regulation of drugs industry as well as pricing of drugs.

15. Member (Industry), Planning Commission and Advisor, Competition Commission of India gave clarifications to the queries raised above. The Chairman thanked them. The witnesses, then, withdrew.

## ORAL EVIDENCE OF SECRETARY GENERAL, INDIAN PHARMACEUTICALS ALLIANCE ON FDI IN PHARMACEUTICALS SECTOR

16. The Chairman welcomed the Secretary General of Indian Pharmaceuticals Alliance on behalf of the Committee and his own behalf. The Chairman, then, apprised him of the concerns of the Committee regarding mergers and acquisitions in pharma sector being carried out through FDI automatic route and sought his

views on the subject and also sought suggestions regarding mergers to streamline the FDI in such a way that it was not harmful for the indigenous pharma industry as well as the people at large.

17. The Secretary General, IPA thanked the Chairman and the Members of the Committee. He, then, gave a presentation on the state of affairs prevalent in pharma industry. He submitted that before 1970 the country imported 80 percent of its drugs requirement and the prices of these drugs were costlier than what prevailed in USA and all Governmental efforts for technology purchase for pharma MNCs failed. He feared that the country was again heading towards that direction only because of the present FDI policy in pharmaceuticals sector.

18. He pointed out that the Maira Committee Report has essentially helped pharma Multi National Companies and suffers many drawbacks. Firstly, the valuation of Indian pharma companies has been reduced. Secondly, by promoting Competition Commission of India it has in effect checked the consolidation of small and medium pharmaceuticals companies. Due to this our pharma companies would remain weak and vulnerable to pharma MNCs.

19. Secretary General, IPA further submitted that channelising FDI in green field projects through automatic route should not be permitted because a company get itself registered with $ 100 million investment but uses it later for various activities without any manufacturing. He suggested that the approval may be automatic but subject to some conditions. It must be ensured that the failure to comply with provisions should attract penalty including cancellation of registration. Foreign investors must also bring in new technology for local production of Active Pharmaceutical Ingredient (API) manufacturing from basic stage. It is important to create API capabilities since we depend on China for 70 percent of our API requirement and our medical security is at stake. It was further submitted that the foreign companies must set up indigenous production of patented medicines which are totally imported today.

20. As regards brown field projects it was stated that all the proposals should be routed through FIPB. Since FIPB served every other sector of our economy so there was no point to exclude pharmaceutical industry from its ambit. It was submitted that it should be made clear to the investors that if they want to come to India and do acquisitions here, then, they have to satisfy certain conditions. Mere acquisition of business without any manufacture and employment should not be allowed. Acquisition is not meant for mere trading. The conditions imposed may entail prohibition on divestment of manufacturing facility for at least 5 years; non-retrenchment of permanent employees for a certain period of years; obtaining prior approval of Health Ministry before discontinuing or curtailing production of any API or formulations placed in the National List of Essential Medicines; and continuation of supply to the domestic market in the same proportion.

21. The Chairman thanked the representative of Indian Pharmaceutical Alliance for his valuable information. He stated that if need arises the Committee would call him again. The witness, then, withdrew.

22. The Committee adjourned at 5.35 P.M.

## IV
## FOURTH MEETING

The Department Related Parliamentary Standing Committee on Commerce met at 11.00 A.M. on, Thursday, the 13th October, 2011 in Committee Room 'A', Ground Floor, Parliament House Annexe, New Delhi.

**PRESENT**

**MEMBERS**

1. Shri Shanta Kumar — *Chairman*

**RAJYA SABHA**

2. Shri V. Hanumantha Rao
3. Dr. E.M. Sudarsana Natchiappan
4. Shri Jai Prakash
5. Shri K.N. Balagopal
6. Ishwarlal Shankarlal Jain
7. Shri Prem Chand Gupta

**LOK SABHA**

8. Shri G.S. Basavaraj
9. Shri K.P. Dhanapalan
10. Shri Shivarama Gouda
11. Prof. Sk. Saidul Haque
12. Smt. Kaiser Jahan
13. Shri Jagdish Sharma
14. Shri Rajaiah Siricilla

**SECRETARIAT**

Smt. Sharada Subramaniam, Joint Secretary
Dr. (Smt.) Subhashree Panigrahi, Joint Director
Shri Amit Kumar, Assistant Director
Shri Rajesh Kumar Sharma, Committee Officer

**WITNESSES**

Shri Mukul Joshi, Secretary, Department of Pharmaceuticals, Ministry of Chemical and Fertilizers
Shri G. Balachandran, Chairman, National Pharmaceutical Pricing Authority (NPPA)
Dr. Raja Sekhar Vundru, Joint Secretary
Shri Devendra Chaudhry, Joint Director

2. The Chairman extended a hearty welcome to all present in the meeting and stated that the Committee is keen to know from the witnesses about the impact of the recent spate of mergers and acquisitions of domestic pharma companies by the multinational companies. There is a growing fear that these overvalued acquisitions in brown field projects will result in a lop-sided growth of the pharmaceuticals industry in the country. This will also adversely impact the access to cheap generic drugs in times to come, affecting the common man. The Committee desired to know in detail about the nature of FDI made in the pharmaceuticals sector; the extent of benefits that have accrued in the form of quality cheap drugs in the country and their amenability to price control mechanism administered by National Pharmaceutical Pricing Authority.

3. To this query, Shri Mukul Joshi, Secretary, Department of Pharmaceuticals replied that the liberalization of Foreign Investment Policy permitted 100% FDI in pharma sector on an automatic route including both green field and brown field investments. Starting from the years 2006-2007 some important Indian companies were bought out completely by foreign companies. These important acquisitions include some of the biggest companies, like, Dabur, Ranbaxy, Shanta Biotech, Piramal, etc. In the years 2008-10, foreign investments suddenly jumped from a couple of hundred million dollars to 5.8 billion dollars.

4. He stated that the whole scenario needs to be carefully looked into and it would be better if a proper study is conducted by a reputed international consultant to understand the whole gamut of issues involved and impact. As suggested by his Department i.e. Department of Pharmaceuticals, a consultant has been appointed

through the Pharma Export Council (PEC). At the same time the Prime Minister's Office also ordered for a high level Committee enquiry under the Chairmanship of Dr. Arun Maira, Member Planning Commission. The core recommendation of the Maira Committee was to keep an eye on FDI and to assess and study its impact on the Indian Pharma Industry in a systematic manner.

5. The Committee was informed that the Department of Pharmaceuticals and the Department of Biotechnology felt that rather than bringing back brown field investments under the Foreign Investment Promotion Board (FIPB) it should be brought under the purview of the Competition Commission of India (CCI) which has come into force w.e.f. 1.6.2011. Department of Pharmaceuticals feels that CCI is the correct authority to examine the cases of mergers and acquisitions. Another important development was that the turnover of acquired companies after mergers increased significantly in 2010. So consequently, it was apprehended that many mergers and acquisitions in pharma sector may not come under that purview due to enhanced turnover limit. Accordingly, at higher level this decision was reviewed and it was decided that the mergers and acquisition in the brown field should come under the purview of the FIPB again for a period of six months till the Competition Commission is in a position to take over the scrutiny. After six months, the position will be reviewed. After that all these mergers and acquisitions, if and when the Competition Commission is ready, shall be subject to the scrutiny thereof.

6. After having heard the views of the Secretary, Department of Pharmaceuticals, the Members of the Committee raised various questions pertaining to the following important issues:-

(i) Why the list of essential and life saving drugs could not be finalized despite being directed by the Supreme Court of India way back in the Year 2003;

(ii) A copy of the report of Ernst and Young be provided. Regarding the antecedents of the multi-national consultancy Ernst and Young, appointed by the Ministry of Commerce and Industry to study the impact of brown field mergers;

(iii) The link between the recent take overs and the hike in prices of drugs;

(iv) Price control on drugs;

(v) Impact on export of pharmaceuticals;

(vi) The number of pending cases before court regarding its faulty/increased pricing (Chairman also directed the Ministry to give the details in writing);

(vii) TRIPS plus protection giving data exclusivity and supplementary protection right for medicinal and plant protection, as these will go against the objectives of Indian Patent Act;

(viii) Helplessness of the National Pharmaceutical Pricing Authority (NPPA) in curtailing high prices of life saving drugs inter-allia including cancer drugs, anti-biotics and nutraceuticals.

7. The Secretary replied to all the above queries and assured to send a written submission with regard to para 6 (vi) above. While concluding he mentioned that pharmaceuticals in India is a 20 billion dollar industry today. The Department expects to grow it to a 100 billion dollar industry and become one of the biggest export industries. For that the pharmaceutical industry should have one window for regulation, pricing as well as promotion. In view of this, he requested the Committee to recommend to the Government so that the DCGI Office be transferred to the Department of Pharmaceuticals. So, also the implementation of Drugs and Cosmetics Act should also be with the Department of Pharmaceuticals.

8. The verbatim record of the proceedings was kept. The meeting of the Committee adjourned at 12.15 pm.

## V
## FIFTH MEETING

The Department Related Parliamentary Standing Committee on Commerce met at 11.00 A.M. on, Thursday, the 21st October, 2011 in Committee Room 'A', Ground Floor, Parliament House Annexe, New Delhi.

**PRESENT**

**MEMBERS**

1. Shri Shanta Kumar — *Chairman*

RAJYA SABHA

2. Shri Jai Prakash
3. Shri K.N. Balagopal
4. Ishwarlal Shankarlal Jain
5. Shri Prem Chand Gupta

**LOK SABHA**

6. Shri G.S. Basavaraj
7. Shri C.M. Chang
8. Prof. Sk. Saidul Haque
9. Shri Jagdish Sharma
10. Shri Rajaiah Siricilla
11. Shri Dinubhai Boghabhai Solanki
12. Shri K. Sudhakaran

**SECRETARIAT**

Smt. Sharada Subramaniam, Joint Secretary
Dr. (Smt.) Subhashree Panigrahi, Joint Director
Shri Amit Kumar, Assistant Director

**WITNESSES**

**REPRESENTATIVES OF DEPARTMENT OF SCIENTIFIC AND INDUSTRIAL RESEARCH**

Prof Samir K. Brahmachari, Secretary, DSIR
Shri V.K. Gupta, Senior Advisor
Shri Zakir Thomas, Project Director

2. The Hon'ble Chairman welcomed the members to the sitting and apprised the Committee about the subject and the representatives to be heard. Thereafter, he welcomed the Secretary and other officials of Department of Scientific and Industrial Research invited for the meeting. Hon'ble Chairman in his opening remarks noted that FDI inflows in the country have predominantly been in brownfield pharmaceutical projects. It was desired that the Committee be informed whether the Research and Development in pharma sector has received any impetus on account of the liberalization of FDI norms. The Chairman also enquired about the initiatives taken by indigenous private enterprises on R&D in tropical diseases and pharmaceuticals, quantum of Government's support for R&D activities in the sector, the extent of reduction in the prices of drugs on account of our R&D initiatives; and our preparedness in the face of the recent spate of acquisitions and mergers of local pharma companies.

3. The Secretary, Department of Scientific and Industry Research informed the Committee that public investment in pharmaceuticals and drug discovery was made in India immediately after independence. Several premier laboratories were built with the purpose of developing processed products for health care. The country also had a large number of public sector pharma companies. Until 1970 multinational companies dominated the international pharmaceuticals trade by taking advantage of the Patent Act of product patent. The change of the Patent Act in 1970 helped in making processed patents and all these laboratories could then

make generic products at a cheaper cost. Accordingly, India emerged as a powerful competitor in the global pharmaceutical market.

4. He referred to the latest development taking place in the pharmaceutical sector and the take over of Indian companies by foreign companies. He expressed his concern that many of these companies sourced their technologies from CSIR laboratories. They benefit from the scientific knowhow and institutional research provided by CSIR, Government subsidy and the tax benefits given by the Government. But, with the latest acquisitions all those benefits have now gone to foreign multinationals. Therefore, acquisitions should always be accompanied with stringent conditions to protect the interest of the people and the country.

5. He mentioned that the right of the patient and the people of India to get drugs at affordable prices is of supreme importance. These companies should fulfill these objectives and obligations primarily and should not stop production of low cost drugs.

6. He also stated that production of life saving drugs is not only important for health care but also of crucial strategic importance from the country's perspective. He cited the example of penicillin as a life saving drug and mentioned that now India is fully dependent on China for penicillin and it is no more produced in the country. This can be used strategically against the country leading anytime to a national crisis. He emphasized that the country should identify and protect important pharmaceutical companies in both private sector and public sector as part of strategic planning and to foremost serve national interest.

7. He also enlightened the Committee about a new strategy being promoted for intellectual property whereby under a non exclusive three tier approach a patent is provided to multiple companies encouraging market competition, leading to affordable and accessible drugs. The Hon'ble Chairman thanked the Secretary for his lucid information.

8. The following concerns/issues were raised during the deliberations of the Committee on which clarifications were sought:-

(i) level of success attained by domestic pharma companies in R&D and the assistance provided by CSIR;

(ii) need for adequate research to develop drugs particularly for Indians and inhabitants of tropical countries;

(iii) preparedness in tackling epidemic diseases that had been phased out but are coming back;

(iv) reasons for public sector units not continuing with vaccine production and dangers of international drug companies supplying vaccines without proper trials;

(v) the approach of CSIR vis-à-vis sectors like Ayurveda and Homeopathy;

(vi) the types of hindrances in the production of new medicines and discovery of new chemical;

(vii) new research especially in the background of gene mutation; and

(viii) future of R&D activity in premium domestic pharma companies after their acquisition by MNCs;

9. The Secretary, DSIR responded to the clarifications sought by the Hon'ble Chairman and the members on the aforesaid issues.

10. The Hon'ble Chairman then thanked the Secretary and his team, DSIR for the valuable and enlightening information provided during the discussion.

11. The verbatim record of the proceedings was kept. The meeting of the Committee adjourned at 12.15 pm.

## VI
## SIXTH MEETING

The Department Related Parliamentary Standing Committee on Commerce met at 11.00 A.M. on, Friday, the 11th November, 2011 in Room No. '63', First Floor, Parliament House, New Delhi.

**PRESENT**

**MEMBERS**

1. Shri Shanta Kumar — *Chairman*

**RAJYA SABHA**

2. Shri V. Hanumantha Rao
3. Shri Jai Prakash
4. Shri K.N. Balagopal
5. Shri Prem Chand Gupta

**LOK SABHA**

6. Shri G.S. Basavaraj
7. Shri Kantilal Bhuria
8. Shri K.P. Dhanapalan
9. Shri Shivarama Gouda
10. Prof. Sk. Saidul Haque
11. Shri Dayanidhi Maran
12. Shri Jagdish Sharma
13. Shri Rajaiah Siricilla
14. Shri Dharmendra Yadav

**SECRETARIAT**

Smt. Sharada Subramaniam, Joint Secretary
Dr. (Smt.) Subhashree Panigrahi, Joint Director
Shri Amit Kumar, Assistant Director
Shri Rajesh Kumar Sharma, Committee Officer

**WITNESSES**

**REPRESENTATIVES OF DEPARTMENT OF COMMERCE, MINISTRY OF COMMERC AND INDUSTRY**

Shri J.S. Deepak, Joint Secretary
Shri Sumanta Chaudhuri, Joint Secretary
Shri Sanjeev Joshi, Director
Shri Narendra Bhooshan, OSD

**REPRESENTATIVES OF INDIA TRADE PROMOTION ORGANISATION (ITPO)**

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**REPRESENTATIVES OF INDIAN MEDICAL ASSOCIATION (IMA)**

Dr. R.N. Tandon, Hony. Joint Secretary

2. * * *

**ORAL EVIDENCE OF REPRESENTATIVES OF INDIA TRADE PROMOTION ORGANISATION (ITPO) ON ACTIVITIES AND FUNCTIONING OF INDIA TRADE PROMOTION ORGANISATION (ITPO)**

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**ORAL EVIDENCE OF REPRESENTATIVE OF INDIAN MEDICAL ASSOCIATION (IMA) ON FDI IN PHARMACEUTICALS SECTOR**

16. The Chairman welcomed the representative of Indian Medical Association (IMA) to the meeting of the Committee. He stated that the Committee would like to know the views of IMA on recent spate of brown field acquisitions by pharma MNCs. The Chairman further observed that one of the main concerns of the Committee while examining the subject 'FDI in Pharmaceuticals Sector' has been to see whether any adverse impact have been caused due to these acquisitions on the availability of cheap medicines to the people. He stated that it was brought to the notice of the Committee that despite the availability of cheap generic drugs, the doctors were rather prescribing expensive branded generics to the patients. The Chairman also stated that the Committee desired to know the views of IMA about the structure of Indian drug industry and the fall-out of FDI on it.

17. Hony. Joint Secretary, IMA thanked the Committee for giving an opportunity to IMA to present its views on the subject. He stated that the quality of FDI that has come in pharmaceuticals sector of the country has not been in the interest of the country. The pharma MNCs on mergers and acquisitions do not display similar concerns like the Indian pharma companies on price control. FDI in green field investments were welcome as it offered some job opportunities and bring in new investments. The medicines of reputed local companies are cheaper by four-five times to those of pharma MNCs. The pharma MNCs charge heavier

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*** Pertains to other matter.

price since they have invested large money in research and development of molecules. However, efficacy of the branded drugs of local companies is same as that of branded generics of pharma MNCs.

18. It was submitted that FDI in pharmaceuticals sector must be subjected to research and trials in Indian circumstances. It was stated that since medical expenditure is predominantly borne by oneself in the country, it is necessary that drugs price are not increased.

19. Members, then, raised their concerns on the following issues and also sought clarifications/suggestions on them:

(i) the reasons as to why the doctors prescribe expensive branded generics when their plain counterparts are easily available;

(ii) the impact of the FDI on the country since India does not have a mechanism for clinical trial like the West and it is more often being used as a trial field;

(iii) the increasing trend of exclusion of drugs from the ambit of Drugs Price Control Order leaving the pharmaceutical companies free to fix the prices of the drugs; and

(iv) whether prescription of generic drugs by doctors may be made compulsory.

20. Hony. Joint Secretary observed that plain generics are successful where the general practitioner is also dispensing medicines within his diagnosis fee. It is also successful in OPDs of hospitals where the dispensary mostly has plain generic medicines and the doctors are not required to write prescriptions. Nevertheless, there is also a market for branded generics and patients would only like to go for them. Here, the psychology that expensive is better than the cheap plays heavy on their minds. It was submitted that though there are no rule binding doctors to prescribe unbranded generics only, yet the doctors try to prescribe cheaper branded generics of good companies to their patients. It is important to create awareness among the people that there is no difference between branded generics and plain generics in terms of efficacy.

21. He further stated that there should be regulation on fixing of Maximum Retail Prices of medicines. This will put a check on arbitrariness in price fixing of medicines. It was informed that IMA is trying to develop a policy where doctors will be advised to prescribe medicines of lower cost and not higher cost patients. Hony. Joint Secretary also drew the attention of the Committee towards the issue of quality control which is better managed in case of branded generics the unbranded generics.

22. The Chairman thanked the witness and conveyed that if required, the Committee may again like to hear the Indian Medical association on the subject. The witness, then, withdrew.

23. The meeting of the Committee adjourned at 1.04 pm. The verbatim record of the proceedings was kept.

## *VIII
## EIGHTETH MEETING

The Department Related Parliamentary Standing Committee on Commerce met at 3.00 P.M. on Tuesday, the 17th January, 2012 in Committee Room 'E', Basement, Parliament House Annexe, New Delhi.

**PRESENT**

**MEMBERS**

1. Shri Shanta Kumar — *Chairman*

**RAJYA SABHA**

2. Prof. P.J. Kurien
3. Shri K.N. Balagopal
4. Shri Y.S. Chowdary

**LOK SABHA**

5. Shri G.S. Basavaraj
6. Shri K.P. Dhanapalan
7. Shri Shivarama Gouda
8. Prof. Sk. Saidul Haque
9. Shri Dayanidhi Maran
10. Shri M.I. Shanavas
11. Shri Jagdish Sharma
12. Shri Rajaiah Siricilla
13. Shri Dinubhai Boghabhai Solanki
14. Shri Modulgula Venu Gopala Reddy

**SECRETARIAT**

Smt. Sharada Subramaniam, Joint Secretary
Shri J. Sundriyal, Director
Shri Amit Kumar, Assistant Director

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* 7th Meeting of the Committee pertain to other matters.

**WITNESSES**

**REPRESENTATIVES OF DEPARTMENT OF ECONOMIC AFFAIRS**

Shri Bimal Julka, Additional Secretary
Shri P.K. Bagga, OSD (CM&Inv)

2. At the outset the Chairman extended his greetings to the Members of the Committee and welcomed them to the first meeting of year. Initiating the discussion on the agenda, he apprised the Members about the changes introduced in the FDI policy in pharmaceuticals sector whereby brownfield investments have been put under government route. He also informed the Members that representatives of the Department of Economic Affairs have been invited to present their views on the subject since the Foreign Investments Promotion Board (FIPB) under its jurisdiction will be the nodal body, for initial six months, to grant approvals to FDI in brown field projects as per the revised policy.

3. The Chairman, then, welcomed Shri Bimal Julka, Additional Secretary and another official of Department of Economic Affairs. He impressed upon them the concerns of the Committee over the prospects of adverse impact of brownfield FDI in pharmaceuticals sector on the availability as well as affordability of cheap generic drugs to the Indian public as many local pharma companies have been acquired by pharma MNCs. He sought to know views of the Additional Secretary on the functioning of FIPB; its preparedness for processing the FDI permissions in pharmaceuticals sector; the constraints in terms of its capacity and delivery mechanism; the recommendations of Maira Committee to replace Foreign Investment Promotion Board with the Competition Commission of India for approval and oversight of brownfield investments in pharmaceuticals sector, etc.

4. The Additional Secretary briefed the Committee on the genesis and working of FIPB. He mentioned that FIPB has been facilitating foreign investments in the country and the Board tries to approve as many FDI proposals as possible, unless, there are large departures in terms of policy or security considerations. The FIPB

also tries to clear proposals at the earliest. He gave a year-wise break up of FDI proposals which have been cleared by the Board since January, 2009. He informed that the rejection rate of FDI proposals by FIPB has not been more than three per cent till date.

5. The Additional Secretary shared the concerns of the Committee on the adverse impact of the acquisition of local pharma companies and informed that the matter has also been engaging the attention of the Government. Elaborating further he informed that in February, 2011 FIPB got a proposal involving investment of Rs. 3300 crores from M/s. Reckitt Benckiser, a UK based company to set up a new wholly-owned subsidiary investing company to make downstream investments in Paras Pharmaceuticals Limited by way of acquisition of its 100 per cent equity. FIPB deliberated on the proposal and recommended it to the Cabinet Committee of Economic Affairs (CCEA). The CCEA while approving the proposal directed that FDI policy in pharma sector be examined by an Inter-ministerial group headed by the concerned Member of the Planning Commission. It directed that the Group should recommend measures for creating an environment conducive to promotion of green field investments in the sector and for positioning India as the leading quality drug research development and manufacturing destination. Accordingly, a Committee was constituted under the chairmanship of Shri Arun Maira, Member (Industry), Planning Commission. It had representatives from the Department of Industrial Policy and Promotion; Department of Pharmaceuticals; Ministry of Health and Family Welfare; Director General, Council of Scientific and Industrial Research; Secretary, Department of Bio-Technology; Chief Economic Adviser of the Ministry of Finance and Drug Controller of India. The Committee deliberated the matter and a report was presented to the Government. Subsequently, in a high-level meeting held under the Chairmanship of the Prime Minister on 10$^{th}$ of October, 2011 it was decided that India will continue to allow FDI without any limit under the automatic route for green field investment in pharma sector. This will facilitate addition of

manufacturing capacity, technology acquisition and development; in case of brown field investments in the pharma sector, FDI will be allowed through FIPB approval route for a period up to six months. During this period, necessary enabling regulations will be put in place by the Competition Commission of India (CCI) for effective oversight on mergers and acquisitions so as to ensure that there is a balance between public health concerns and promotion of FDI in the pharma sector. Thereafter, the requisite oversight will be done by the CCI entirely in accordance with the competition laws of the country.

6. The Additional Secretary shared that after the changed policy, the FIPB has received five proposals out of which four proposals were considered in December, 2011 and the Board was awaiting inputs from Ministry of Health and Family Welfare and Department of Pharmaceuticals before giving the final nod to them. He informed that aggregate inflow of foreign investments expected out of these proposals is to the tune of approximately Rs.270 crores.

7. After hearing the preliminary presentation of the witnesses, the following concerns/ issues were raised by the Members of the Committee:-

i. the reasons as to why there has been very little greenfield FDI in pharmaceuticals sector since only one green field investment has come to the country compared to several brownfield investments in the sector;

ii. whether FIPB has any mechanism to ensure that pharma MNCs getting clearance for brownfield investments do not shift their focus from the low cost domestic market to remunerative global market;

iii. whether putting FDI in brownfield pharma projects through government route will assure availability of cheap generic drugs in the country;

iv. whether enhancement in capacity addition would be taken into account by FIPB while examining the FDI proposals for brown field investments;

v. the negative spill over, if any, that may result on account of high valuation takeovers in the pharma sector;

vi. whether the local pharma companies gave any undertakings to the acquiring companies to stay away from pharma business in order to stave off competition for the acquiring foreign pharma companies;

vii. the power of FIPB, if any, in tempering the decisions of those MNCs acquiring domestic companies, as regards production profile of drugs and determination of their prices;

viii. the impact of FDI in brownfield pharma projects on the domestic pharmaceutical industry especially in view of the fact that a large number of drugs were going off patent in short time;

ix. the extent of FIPB's oversight to ensure manufacturing activities by pharma MNCs post entry of foreign investment;

x. the urgent need for better co-ordination among various Government Departments so as to provide an effective check on the pharma MNCs from exploiting policy ambiguities;

xi. the extent to which the FIPB mechanism can ensure that Foreign Investment flow into the country enhances the overall welfare of the country; and

xii. the views of FIPB on the recommendations of the Hathi Committee stating that technically competent domestic pharma companies be encouraged to produce antibiotics and life saving drugs rather than permitting the MNCs to venture into it.

8. The Additional Secretary gave clarifications on the concerns/ issues raised above. He mentioned *inter-alia* that FDI under automatic route for any sector as well as concerns attached to those FDIs are looked into by the concerned Departments. FIPB intervenes only in those investments which deviate from Foreign Exchange Management Act (FEMA) regulations. He also informed the Committee that the high valuation takeovers and the apprehended adversities that come alongwith it had not been brought to FIPB's notice.

9. The Chairman thanked the Additional Secretary and the other official of the Department of Economic Affairs for the valuable information. He observed that the Secretariat would send them a detailed questionnaire including the queries

which remained unanswered on this subject for written reply there to. The witnesses then withdrew.

10. A verbatim record of the proceedings was kept. The Committee adjourned at 3.55 p.m.

## IX
## NINETH MEETING

The Department Related Parliamentary Standing Committee on Commerce met at 11.00 A.M. on Wednesday, the 18th January, 2012 in Committee Room 'E', Basement, Parliament House Annexe, New Delhi.

**PRESENT**

**MEMBERS**

1. Shri Shanta Kumar — *Chairman*

**RAJYA SABHA**

2. Dr. E.M. Sudarsana Natchiappan
3. Shri Jai Prakash
4. Shri K.N. Balagopal
5. Shri Prem Chand Gupta
6. Shri Y.S. Chowdary

**LOK SABHA**

7. Shri G.S. Basavaraj
8. Shri Shivarama Gouda
9. Prof. Sk. Saidul Haque
10. Shri Dayanidhi Maran
11. Shri Jagdish Sharma
12. Shri Rajaiah Siricilla

**SECRETARIAT**

Smt. Sharada Subramaniam, Joint Secretary
Shri J. Sundriyal, Director
Shri Amit Kumar, Assistant Director

**WITNESSES**
**REPRESENTATIVES OF COMPETITION COMMISSION OF INDIA**

Shri Ashok Chawla, Chairperson
Shri P.K. Purwar, Adviser (FA)

**REPRESENTATIVES OF THE UNITED PLANTERS' ASSOCIATION OF SOUTHERN INDIA (UPASI)**

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2. The proceedings of the meeting commenced with opening observations by the Chairman wherein he welcomed the Members of the Committee and informed them about the agenda for the day.

## I. ORAL EVIDENCE OF REPRESENTATIVES OF COMPETITION COMMISSION OF INDIA ON FDI IN PHARMACEUTICALS SECTOR

3. The Chairman welcomed Shri Ashok Chawla, Chairperson, CCI and his colleague to the meeting and shared the concerns of the Committee over the high value takeovers/ mergers/ acquisitions of domestic pharma companies by the pharma MNCs. He observed that these mergers/acquisitions might result in steep rise in the price of the pharmaceuticals in India as also the problem of access and affordability of medicines to the majority population. He sought to know the necessity for regulation in view of the country being a welfare state. He wanted the Chairperson to brief the Committee about Commission's preparedness to promote and sustain competition in pharmaceuticals sector without endangering the consumers' right of getting drugs at affordable price and the constraints being faced by the Commission in terms of its capacity and delivery mechanism. The Chairman further sought to know about the structural competence of CCI to bind the pharma MNCs with the obligation to continue the R&D activities even after acquisition of domestic companies.

4. The Chairperson, Competition Commission of India gave an overview of the mandate of the CCI. He informed that under the provisions of the Competition

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*** Pertains to other matters

Act, 2002, the Commission aims to prevent practices having adverse effect on competition, take steps to promote and sustain competition in the markets and also protect the interests of the consumers. The Act also empowers the Commission to address the issues of dominance and the abuse of dominance. It requires the companies to seek prior approval of mergers and acquisitions above a specified threshold from the Commission. The provision regarding prior approval applies to all classes of enterprise or companies in any sector. He, however, expressed his concern that the threshold level envisaged for prior approval of mergers and acquisitions was high and the target companies or enterprises having an asset base less then Rs. 250 crore or a turnover less than Rs. 750 crore were exempted from seeking approval from the Commission.

5. The Chairperson mentioned that 21 cases of mergers/ acquisitions came before the Commission during the period from 1st June to 31st December, 2011, but none of them pertained to the pharmaceuticals sector. Explaining the process of filing applications for prior approval, he informed that the Commission decides a case within thirty days as laid down in the Act. In cases where a more detailed scrutiny is required, another 180 days extension is permissible. Thus, total time available to the Commission was 210 days. While deciding the cases for approval, the Commission look into the structure of the industry concerned; the structure of the companies and their market share; contours of the proposed transaction, post approval shape of the market and the likely benefits to the market and the consumers.

6. He apprised that a High Level Committee set up under a Member of the Planning Commission has gone into the issue of FDI in pharmaceuticals sector and submitted its report to the Government. The said Committee, has, *inter-alia*, made three recommendations viz. (i) that the exemption in terms of threshold level for prior approval for mergers and acquisitions from 'target company enterprise' should be withdrawn so far as the pharmaceuticals companies were concerned; (ii) that the

fifty per cent increase in the threshold limit which was given across the board at the time the provisions were enforced, needs to be 'revisited'; and (iii) a Standing Advisory Committee on Health should be set up to technically assist the Competition Commission to look at cases of mergers and acquisitions in pharma sector.

7. During his presentation, the Chairperson categorically submitted that unless there was a specific change in the provisions of the Competition Act regarding threshold limits, the Act may not prove to be an effective instrument of oversight on foreign entities buying in the existing plants in the pharma sector. He informed that if the Competition Commission finds that operation of a company, after approval, is harmful to competition, then it is empowered to put a check on the operations of the company at subsequent stage. The Chairperson submitted that the Competition Commission was equally keen to look at availability and pricing of essential drugs for the benefit of consumers.

8. After the presentation, the Members raised the following issues and sought clarifications:-

(i) whether the CCI is competent to protect the interest of consumers in case of formation of cartels under the guise of bringing in increased efficiency in production process;

(ii) the detailed process of selection of Members of Standing Advisory Committee on Health and whether the recommendations of the Committee will be binding on the Commission;

(iii) whether the CCI has structural competence to provide effective oversight on proposed mergers/acquisitions in pharmaceuticals sector and protect the interests of consumers;

(iv) whether the CCI has any mechanism to ensure that profiteering is not resorted to by business companies;

(v) whether CCI has taken any action under ‘Appreciable Adverse Effect on Competition’ clause on account of recent spate of acquisitions of domestic pharmaceuticals companies resulting in distortion of market structure and causing adverse impact on healthcare in general;

(vi) whether the CCI have any specialized wing to check that FDI which has come on the pretext of R&D and innovation does not go into production and marketing of its product;

(vii) whether the CCI have the mandate to put conditions like price ceiling before allowing FDI for mergers and acquisitions;

(viii) whether framing an FDI policy separately on bulk drugs and separately on formulations would be effective;

(ix) the procedure to approach the CCI for making complaints and the level of transparency practiced by the Commission; and

(x) the amendments desired by the Competition Commission to the existing Act so as to make it an effective institution.

9. The Chairperson replied to the queries of the Members. The Chairman, then, thanked him and his colleague for the valuable information. He observed that the Secretariat would send them a detailed questionnaire on the subject for written reply thereto. The witnesses, then, withdrew.

## II. ORAL EVIDENCE OF REPRESENTATIVES OF THE UNITED PLANTERS' ASSOCIATION OF SOUTHERN INDIA (UPASI) ON PERFORMANCE OF PLANTATION SECTOR-TEA AND COFFEE INDUSTRY

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21. A verbatim record of the proceedings was kept. The Committee adjourned at 1.20 p.m.

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*** Pertains to other matters

## X
## TENTH MEETING

The Department Related Parliamentary Standing Committee on Commerce met at 11.00 A.M. on Wednesday, the 25th January, 2012 in Committee Room 'G074', Ground Floor, Parliament Library Building, New Delhi.

**PRESENT**

**MEMBERS**

1. Dr. E.M. Sudarsana Natchiappan (In the Chair)

**RAJYA SABHA**

2. Shri K.N. Balagopal
3. Shri Prem Chand Gupta

**LOK SABHA**

4. Shri C. M. Chang
5. Prof. Sk. Saidul Haque
6. Shri Dayanidhi Maran
7. Shri Vishnu Deo Sai
8. Shri M. I. Shanavas
9. Shri Jagdish Sharma
10. Shri Rajaiah Siricilla

**SECRETARIAT**

Smt. Sharada Subramaniam, Joint Secretary
Shri J. Sundriyal, Director
Shri Amit Kumar, Assistant Director

**WITNESSES**

**REPRESENTATIVES OF FEDERATION OF MEDICAL AND SALES REPRESENTATIVES' ASSOCIATION OF INDIA (FMRAI)**

Shri D. P. Dubey, General Secretary
Shri Amitava Guha, Member, Working Committee
Shri H. Syal, Member, Working Committee

**ORAL EVIDENCE OF REPRESENTATIVES OF FEDERATION OF MEDICAL AND SALES REPRESENTATIVES' ASSOCIATION OF INDIA (FMRAI)**

2. In the absence of the Chairman, Dr. E.M. Sudarsana Natchiappan chaired the meeting of the Committee. He welcomed the Members and apprised them about the agenda for the day.

3. Thereafter, he welcomed the General Secretary and other representatives of Federation of Medical and Sales Representatives' Association of India (FMRAI). Initiating the discussion, the Chairman expressed concern regarding over-valued acquisition of domestic pharmaceuticals companies by pharma MNCs and its adverse effect on the availability of cheap generic drugs to the public. He expressed apprehension that brownfield investments would impact the orientation of research and development activities of the acquired companies in terms of lesser emphasis on R&D for tropical diseases. He sought to know the marketing strategies and behavioral patterns of foreign pharma companies and local pharma companies, the efficacy of unbranded generic drugs in comparison to branded ones and the steps necessary for promotion of unbranded generic medicines in the country.

4. The General Secretary, FMRAI submitted that they opposed 100% Foreign Direct Investment (FDI) in the pharma industry. He argued that experience had shown that before the establishment of central PSUs, like, the Hindustan Antibiotic Limited and the IDPL, the drug MNCs were least concerned about the availability of medicines and low drug prices. It was only with the operation of these PSUs, that pharma MNCs were forced to reduce the drug prices and also establish factories in our country.

5. It was submitted that India was self-reliant in drug production and was known for cheapest prices of drugs in the world but with neo liberal economic policies in place and the closure or virtual closure of Public Sector Units (PSUs) in the pharma sector the situation had changed, with significant proportion of Indian

pharmaceuticals market being rapidly acquired by drug MNCs. Prior to recent takeovers and acquisitions, the pharma MNCs controlled 19 per cent of the total market share which has since increased to 28.46 per cent and the continuation of FDI in brownfield pharma projects may result in to shift of 50 per cent of the total market to pharma MNCs. It was submitted that the declining market in developed countries and the immense growth potential in India were the major reasons for the pharma MNCs eyeing the Indian market. Other attractions included the opportunity to utilize the domestic marketing network of the Indian companies, exploit the lax regulatory system prevailing in the pharmaceuticals sector and to capture the existing export market painstakingly built up by the Indian companies.

6. The Committee was informed that since 2007, FDI worth Rs. 50000 crores has come through acquisition route without any industrial investment. The witnesses pointed out the lackadaisical attitude of pharma MNCs towards industrial investment. Till 2010, MNCs investments in plant and machinery has been only 5 % of the investments of Rs. 1,37, 652.50 million made by the Indian companies. Also, this data when taken at current prices suggest that real investment by MNCs have fallen in absolute terms. The MNCs investments at 1994 prices has shown a decline from Rs.4,555.10 million in 1994 to Rs. 465.6 million in 2009.

7. Explaining the nature of operations of pharma MNCs, the FMRAI representatives submitted that the MNCs in the pharma sector completely relied on third-party manufacturing under the loan licensing system while they concentrated in the area of sales promotion or marketing. Such a trend indicates that availability as well as affordability of pharmaceuticals would be completely in the hands of pharma MNCs. They opined that pharmaceutical was a commodity distinctly different from other commodities where the purchaser had no choice but to buy what is prescribed. The unique feature of medicines was fully exploited by the MNCs through unfair marketing amongst the medical practitioners. The Indian laws were violated regularly by MNCS which increased the drug prices in pursuit

of high profit. By acquisition routes the MNCs were in the process to capture the large export markets of Indian pharmaceuticals. It was also informed that there are evidences to show that pharma MNCs were practically putting every obstacles into the development of R&D mechanism emphasizing on local diseases.

8. After hearing the preliminary presentation of the witnesses, the following concerns/ issues were raised by the Members of the Committee:-

(i) whether pharma MNCs have operated simultaneously with Central Public Sector Units (CPSUs) in the Pharma Industry. If so the extent of adverse impact pharma MNCs' presence had on the operations of pharma PSUs resulting in their closure;

(ii) the violations, legal or otherwise, committed by the pharma MNCs after entering the country;

(iii) whether any study has been conducted by FMRAI to evaluate the effect of MNCs/FDI in the pharma sector items of employment opportunities, research and development etc.;

(iv) whether FDI policy has resulted in competition amongst the pharma MNCs and domestic pharma companies resulting in reduction in drugs price;

(v) whether the revised National List of Essential Medicines containing 348 drugs be brought under the Drug Price Control Order, 1995 so as to control the price of drugs;

(vi) efficacy of the policy of allowing 100% FDI in Greenfield projects for technological development, research and development, job creation, discovery of new medicines;

(vii) the likely impact of TRIPS plus situation, data exclusivity and market exclusivity on the pharma sector in general and consumers in particular;

(viii) what are the solutions to address the problem posed by huge production of bulk drugs and formulations by China and sold in the international market and how effective will be the policy of not allowing FDI into bulk drungs production;

(ix) the extent of failure of State Governments to check violations committed by MNCs and confusions prevailing about drugs laws;

(x) the efficacy of the proposal to strengthen the drugs price control mechanism to ensure that consumer is given topmost priority;

(xi) the efficacy of the proposal to revive the pharma PSUs or begin afresh with the State involving itself into production of medicine so as to protect the interests of consumers.

10. The representatives of FMRAI gave clarification on the issues raised. The Chairman, then, thanked the representatives of FMRAI for the information provided. The witnesses, then, withdrew.

11. A copy of the verbatim record of the proceedings was kept. The Committee adjourned at 12.08 p.m.

## XI
## ELEVENTH MEETING

The Department Related Parliamentary Standing Committee on Commerce met at 4.00 P.M. on Monday, the 6th February, 2012 in Committee Room 'E', Basement, Parliament House Annexe, New Delhi.

**PRESENT**

**MEMBERS**

1. Shri Shanta Kumar — *Chairman*

**RAJYA SABHA**

2. Prof. P.J. Kurien
3. Shri K.N. Balagopal
4. Shri Prem Chand Gupta

**LOK SABHA**

5. Shri G.S. Basavaraj
6. Shri Kantilal Bhuria
7. Shri K.P. Dhanapalan
8. Shri Shivarama Gouda
9. Prof. Sk. Saidul Haque
10. Shri Dilip Singh Judev
11. Shri Dayanidhi Maran
12. Shri Jagdish Sharma
13. Shri K. Sudhakaran

**SECRETARIAT**

Smt. Sharada Subramaniam, Joint Secretary
Shri J. Sundriyal, Director
Shri Amit Kumar, Assistant Director

**WITNESSES**

**REPRESENTATIVES OF CENTRE FOR TRADE AND DEVELOPMENT (CENTAD)**

Shri K.M. Gopakumar
Shri Santosh M.R.
Ms. Ranja Sengupta

**ORAL EVIDENCE OF REPRESENTATIVES OF CENTRE FOR TRADE AND DEVELOPMENT (CENTAD)**

2. At the outset, the Chairman welcomed the Members of the Committee and apprised them about the agenda of the meeting. Thereafter, he welcomed Shri K.M. Gopakumar and other representatives of the Centre for Trade and Development (CENTAD) and shared the concerns of the Committee over the impact of FDI in Pharmaceuticals Sector especially brownfield investments in terms of availability and affordability of medicines to the Indian public at large as well as decimation of the domestic pharma industry. The Chairman sought to know the inherent flexibilities in national and international laws that can be used to tackle the issues of inaccessibility of medicines and whether any policy of the Government has helped the pharma MNCs exploit local conditions to the detriment of public health and domestic pharma industry.

3. Shri Gopakumar submitted that in the absence of policy intervention, the ability of Government to ensure access to medicine as guaranteed under Article 21 of the Constitution of India would be compromised. To him self-sufficiency in pharmaceuticals lies in control by the Government. Lack of enabling policy environment, absence of robust public sector, introduction of product patent regime, entry of new costly medicines with MNC monopoly-prohibitive prices, increasing import dependence, increasing licensing deals, strategic alliance, contract research, free trade agreements, global IP architecture and FDI in pharmaceuticals are few of the threats to self-sufficiency. He added that FDI in

Pharmaceuticals Sector should promote the unmet needs of the industry and that FDI is not required in manufacturing, distribution etc.

4. It was submitted that acquisitions of Indian pharma companies by the MNCs has captured the distribution network of Indian generic companies. The self-reliance and medical security of the country have been severely compromised due to vested interest of the MNCs in import-based market structure causing trade imbalance and higher trade deficit. The Committee was also informed that the drive for acquisitions/mergers by the pharma MNCs was fuelled by their own business interest for further expansion and their desire to restructure strategies for business growth, the FDI thus coming into the country was incapable of meeting the health needs of the country.

6. During the course of the presentation, the representatives of CENTAD also pointed out the short comings of the Maira Committee. On the role of the CCI, the representatives informed that CCI cannot oversee all brownfield investments without amending the existing Competition Act. It was argued that the concerns emerging out of FDI in brownfield should be tackled through policy tools and not through statutory bodies like CCI since the Commission's approach to the issue is from a competition point of view and not in context of public policy in particular.

7. After hearing the presentation of the witnesses, the following concerns/issues were raised by the Members of the Committee:-

(i) the reasons which led to the closure of public sector undertaking related to pharmaceutical;
(ii) suggestions for the revival of closed public undertakings like HAL and IDPL;
(iii) effect of acquisitions of Indian pharma companies by the MNCs on the domestic market as regards the introduction of new products were concerned;
(iv) impact of process patent regime to product patent regime since 2005 on the drug Industry;

8. The Chairman thanked the representatives of Centad for their inputs on the subject under deliberation and asked them to send additional information to the Committee in writing. The witnesses, then, withdrew.

9. * * *

10. A copy of the Verbatim record of the proceedings was kept. The Committee adjourned at 5.50 p.m.

*** Pertains to other matters

## *XIX
## NINETEENTH MEETING

The Department Related Parliamentary Standing Committee on Commerce met at 11.30 A.M. on Tuesday, the 29th May, 2012 in Committee Room 'A', Ground Floor, Parliament House Annexe, New Delhi.

**PRESENT**

**MEMBERS**

1. Shri Shanta Kumar — *Chairman*

**RAJYA SABHA**

2. Prof. P.J. Kurien
3. Shri K.N. Balagopal
4. Shri Ishwarlal Shankarlal Jain
5. Shri Prem Chand Gupta
6. Shri Rangasayee Ramakrishna
7. Shri Kiranmay Nanda

**LOK SABHA**

8. Shri G.S. Basavaraj
9. Shri C.M. Chang
10. Shri K.P. Dhanapalan
11. Shri Shivarama Gouda
12. Prof. Sk. Saidul Haque
13. Smt. Kaiser Jahan
14. Shri Dayanidhi Maran
15. Shri M.I. Shanavas
16. Shri Jagdish Sharma
17. Shri K. Sudhakaran
18. Shri K. Jayaprakash Hegde

**SECRETARIAT**

Smt. Sharada Subramaniam, Joint Secretary
Shri J. Sundriyal, Director
Shri Amit Kumar, Assistant Director

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* 12th to 18th Meetings of the Committee pertain to other matters.

**WITNESSES**

**REPRESENTATIVES OF DELHI SOCIETY FOR PROMOTION OF RATIONAL USE OF DRUGS (DSPRUD)**

Dr. Usha Gupta, Executive Vice President

Dr. Nirmal Kumar Gurbani, Executive Member

2. At the outset, the Chairman welcomed the Members to the meeting. *** He, then, informed the Committee that the representatives of Delhi Society for Promotion of Rational Use of Drugs (DSPRUD) have been invited to present views on the subject 'FDI in Pharmaceuticals Sector'.

3. Welcoming the representatives of DSPRUD he sought their views on the issues concerning FDI in pharmaceuticals sector in the context of country's social and cultural milieu, quality of FDI inflow in green field and brown field pharma projects, impact of recent brown field mergers/acquisitions/takeovers on domestic pharma industry, investments in R&D and technology transfer due to FDI in the sector, the likely impact of FDI on drug prices, efficacy and structure of regulation mechanism in the form of FIPB/CCI. He further desired to know the structure of the pharma industry and its social responsibility in ensuring availability of cheap drugs, policies of the Government, if any, which led to exploitation of local conditions by the MNCs, inherent flexibilities in national and international laws that can channelize FDI to address the problem of inaccessibility of medicines etc.

4. Dr. Usha Gupta, the Executive Vice President of DSPRUD gave a brief overview of the activities undertaken by the organization for promoting the rational use of medicines amongst the stake-holders. She submitted that the impact of FDI in pharmaceuticals sector could be gauged through certain parameters like its

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*** Pertains to other matters

contribution in production and development of drugs specific to local diseases which are not being produced in the country, technology transfer and consequent development of new drugs, availability of quality drugs at affordable price, reduction in price of drugs, affordability and availability of drugs. She opined that FDI has failed to bring any advantage on all these parametres. It was submitted that there was a lack of effective quality control on drugs in the country and the main reason for high price of medicines were the doctors who prescribe drugs of expensive brands despite the availability of affordable generic varieties. She emphasized on the need for a strong pharmaceutical regulatory authority to ensure availability of quality drugs at reasonable price in the country. It was argued that such an authority should be de-linked from the Drugs Controller General of India (DCGI) which was otherwise also grappling with many other issues. She expressed apprehensions that FDI was being prescribed for the sake of ensuring supply of quality drugs in the market. She submitted that if more than 100 domestic pharma companies can export generics after complying to high quality norms then why can't they supply the same quality drugs in domestic market. She added that support may instead be extended to augment capability and regulate quality norms of domestic pharma companies on the lines of United States Food and Drug Administration (USFDA). She suggested that FDI may be allowed but to a certain limit after weighing its advantages and disadvantages on the industry. The Committee was apprised that free treatment and free medication can be provided to the masses without increasing the budgetary allocation of funds. The case of Delhi State's Generic Drugs Policy was cited whereby essential drugs were still being provided with a budget outlay that was fixed in the year 1994.

5. After hearing the preliminary presentation of the witnesses, the following concerns/ issues were raised by the Members of the Committee:-

i the reasons for misuse/ excessive use of allopathic drugs and the ways and means to address this problem;

ii the framework required to ensure availability of drugs within reasonable price;

iii mechanisms to discourage doctors from prescribing expensive drugs and encourage them to prescribe generic drugs;

iv ways to check the practice of extending incentives to doctor for promotion of a drug by the pharma companies;

v utility of 'Jan Aushadi Kendras' in serving the large Indian population;

vi the reasons for absence of professionals and technical experts in the regulatory authorities panels;

vii the need to create an educational platform providing detailed information about names, price, availability, compositions, contraindication etc. of all branded drugs in the market;

viii quality of functioning of Central Drugs Standard Control Organisation;

ix preference for branded drugs over generic drugs by the public;

x educating the doctors about the effectiveness and quality of generic drugs compared to the branded drugs by which the generic revolution would eventually reach the people;

xi ways to inculcate faith amongst the masses about the quality and effectiveness of generic drugs;

xii effective functioning of National Pharmaceuticals Pricing Authority effective and control over pricing of drugs by pharmaceutical companies; and

xiii mechanism to plug the sale of spurious drugs and effectiveness of legislation on such sales.

6. The witnesses then responded to the aforesaid issues/ concerns raised by the Committee. The Chairman thanked the representatives of DSPRUD for the valuable information on the subject and asked them to send additional information to the Committee in writing. The witnesses then withdrew.

7. * * *

8. A record of the proceedings was kept.

9. The Committee then adjourned at 12.32 p.m.

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*** Pertains to other matters

## *XXI
## TWENTY FIRST MEETING

The Department Related Parliamentary Standing Committee on Commerce met at 11.00 A.M. on Thursday, the 21st June, 2012 in Room No. 'G074', Ground Floor, Parliament Library Building, New Delhi.

**PRESENT**

**MEMBERS**

1. Shri Shanta Kumar — *Chairman*

**RAJYA SABHA**

2. Shri V. Hanumantha Rao
3. Dr. E. M. Sudarsana Natchiappan
4. Shri K. N. Balagopal
5. Shri Ishwarlal Shankarlal Jain
6. Shri Kiranmay Nanda

**LOK SABHA**

7. Shri G.S. Basavaraj
8. Shri K.P. Dhanapalan
9. Shri Shivarama Gouda
10. Prof. Sk. Saidul Haque
11. Shri Dayanidhi Maran
12. Shri M.I. Shanavas
13. Shri Rajaiah Siricilla
14. Shri K. Sudhakaran
15. Shri K. Jayaprakash Hegde

**SECRETARIAT**

Smt. Sharada Subramaniam, Joint Secretary
Shri J. Sundriyal, Director
Shri Amit Kumar, Assistant Director

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* 20th Meeting of the Committee pertains to other matters.

**WITNESSES**

Shri Aamir Khan
Dr. Gulati
Dr. Samit Sharma
Ms. Svati
Mr. Lancy Fernandes

2. At the outset, the Chairman welcomed Shri Aamir Khan and his colleagues to the meeting. He complemented Shri Aamir Khan for raising issues that have a direct bearing on the lives of common man through his TV programme 'Satyamev Jayate'. He felicitated Shri Khan and his team on accepting the invitation of the Committee to deliberate on the subject ’FDI in Pharma Sector’- an issue of immense public concern. Shri Aamir Khan thanked the Chairman for inviting him and his colleagues to present their views on the subject.

3. Initiating the discussion, the Chairman gave a brief overview of the pharma sector tracing the intellectual property regime in the sector, and the recent acquisitions of domestic pharma companies and its likely implications on generic medicines. He sought to know whether it was mandatory under the W.T.O regime to permit FDI in the Pharma Industry, the reasons for preference for highly priced branded medicines by the public, the reasons as to why doctors do not prescribe generic drugs in violation of Medical Council of India regulations and other problems affecting accessibility of medicines at affordable prices to general public.

4. Admitting that the concerns raised needed urgent attention, Dr. Gulati made a powerpoint presentation touching upon various aspects of healthcare and issues pertaining the subject 'FDI in pharmaceuticals Sector'. He emphasised that treatment and medicines were integral to the Right to Life and India should avoid dependence on foreign sources including companies for the supply of medicines and vaccines to its people. He shared that 82.7% of out of pocket expenses of the Indian public was spent on healthcare and treatment. India is the fourth highest

spender of out of pocket money on health care and according to NSSO, expenditure on chronic treatment is a major case of rural indebtedness. This was in complete contrast to Belgium where the healthcare expenses of its citizens are borne by the State. He advocated for an increase in the health budget of the country which currently stood at meagre 1.4% of GDP.

5. Dr. Gulati conceded that medicines were not just like other consumable items and they are required to maintain life and it was the responsibility of the State to ensure affordable medicines accessible to the Indian public which was possible only with the help of a vibrant domestic drug industry. According to him, foreign sources could not be relied upon for supply of affordable medicines and rather dependence on them would have adverse effects on India. He informed that foreign companies were capturing the raw materials markets of essential drugs leading to monopoly and endangering the supply of raw material to our domestic industry.

6. Dr. Gulati apprised that the pharma industry in India has 10,500 units out of which 2,000 units produced bulk drugs. The domestic industry consists of large, medicinal and small scale industrial units. He added that post-liberalisation, a large number of MNCs have entered India and they instead of creating manufacturing facility have rather opened marketing offices and were merely importing and trading or at the most they get some of their brands manufactured by the domestic SSI units. He argued that the possibility of new large scale foreign pharmaceutical manufacturer entering the domestic market appeared bleak and with the existing domestic units being bought by MNCs, India would have no competitive capability to produce technologically advanced molecules.

7. According to Dr. Gulati, a significant portion of the top 15 companies were in the foreign hands today. In the 1970s, 85% of the drugs were marketed by the MNCs and the remaining 15% was catered by the domestic units but by the 1990s this trend was reversed. This trend reversal was due to various policy interventions like policy favouring process patent to product patent, preferential treatment to

domestic units in terms of lower income-tax, licensing, etc.; fixing 40 per cent or less foreign shareholding for companies under Foreign Exchange Regulation Act (FERA), 1974 to avail various benefits and preferential treatment; industrial licensing policy; import policy; sops for SSI units and establishment of Public Sector Undertakings like Hindustan Antibiotics Limited, Indian Drugs and Pharmaceuticals Limited to manufacture both bulk drugs and formulations. To him, the restricted foreign shareholding under Foreign Exchange Regulation Act (FERA), 1974 aided the development of the Indian industry.

8. Allaying the fears expressed in some quarters that tweaking the FDI policy will create negative press, Dr. Gulati argued that the Indian pharma industry grew by 22 percent in the year 2011 where as the American industry witnessed deceleration. Thus, India offered huge opportunities to the pharma industry and is always in a position to dictate terms if she so desired and subject to right-policy decisions. He pointed out that the Import Policy which earlier had built in graded incentive system to start manufacturing in India has in recent times been diluted to provide the pharma MNCs the opportunities to exploit the market conditions by importing the drugs. He also blamed the post-reform policies like replacement of FERA with a watered down FEMA, introduction of Product Patent, acquisition of more than half a dozen domestic drugs units by MNCs due to the 100% FDI in pharma sector through automatic route, lesser attention to PSU drug units which are under performing for downfall of domestic pharma industry. To him, the nation was losing out in the exports due to takeovers of domestic companies by MNCs and as a result MNCs now account for more than 25% of the market. Indian companies were surrendering their export markets to the acquiring MNCs eventually piping the Indian exports. He deplored the creeping dependence of domestic pharma companies on MNCs due to commercial deals and this dependence on MNCs would impede the utilization of compulsory license during an emergency situation.

9. He was of the opinion that the current drug pricing procedure hurts the domestic sector but helps MNCs. Domestic manufacturers are subject to Drug Price Control Order (DPCO) for 74 drugs while other molecules are outside the price regulation but subject to ceiling of 10% annual increase in the price. He shared that MNCs have three categories instead of two in their portfolio: the third category being patented, imported ready-to-use formulations which are totally outside price regulation. MNCs are also permitted to import raw material (from their parent and/or associated companies abroad) at non-verifiable rates. Thus MNCs benefit by raking in huge profits not only on uncontrolled patented, imported formulations but also on non-scheduled formulations due to inflated invoices of raw material and/or higher base price. For example while Torrent is permitted to hike the price of Risperidone from Rs. 17 to Rs. 18.70, MNC Ethnor (J&J) can hike the price of the same drug from Rs. 270 to Rs. 297. Thus the annual permitted increase of Rs. 27 alone is more than the MRP of its competitor. Since patients do not decide the brand, there is no price resistance. He then pointed out the anomaly in Rule 10P of the Drug Price Control Order which says 10 per cent is the maximum a company can increase the price of a drug in a year but does not talk about base price. He informed that the prices of drugs produced and marketed by MNCs were much higher that domestic drugs. In India the highest priced drug was sold more than the lowest priced drug since the patients have no control over the choice of brands and they rely completely on doctor's prescription. He apprised that since 2003, over 1,277 "Registration Certificates" have been issued to import finished formulations. Many of them are patented drugs sold at monopoly prices. Traders are importing and selling directly to patients on tips from doctors. There is no regulation or monitoring on the prices and no obligation to manufacture in India. He appealed that lawmakers should make it mandatory for the MNCs to manufacture in the country.

10. Dr. Gulati mentioned that R&D issue in Indian pharma industry has always remained on the backburner. India should be able to invent new molecules, patent

them and sell them globally which in itself is a very difficult exercise. In the last 63-64 years, only four new drugs have been produced out of which one is highly doubtful. India is yet to develop the capability of clinical testing. He was critical of the fact that Indian income tax law does not distinguish between result oriented R&D and R&D efforts. Concessions are being doled out to research units but there are no results to see in the terms of a new molecule or formulation. Pharmaceutical research is step-by-step process. Many individual steps can be commercially exploited. Many large US innovators buy a new promising molecule from small innovators at an early stage and then develop them into commercially viable drugs (including clinical trials). A foreign company operating in India can transfer early research to its parent company abroad. The same drug were then sold to Indians at very high global prices. He submitted that this has led to despondency amongst domestic promoters. He argued that unless policies are changed soon enough, the domestic sector may not be able to survive in the environment heavily tilted in favour of MNCs who will become predators. He cited the example of Ranbaxy where two of the three heirs of original Ranbaxy have quit the pharma field while the third one has sold the business to the Japanese and other companies like Surya Pharma are getting into cash and carry business.

11. Dr. Gulati opined that the review of the 100 per cent automatic FDI in pharma industry has been half hearted and diversionary. According to him, the terms of reference of the Committee of the Planning Commission which examined the FDI policy were extremely narrow. The crucial core issue of perpetual dependence on foreign sources was not even considered, much less addressed. The Government decided to refer only "brownfield" acquisitions to the Competition Commission of India (CCI) leaving the doors open to MNCs to open marketing entities with emphasis on imports and zero manufacturing facilities. He submitted that CCI has neither powers, nor expertise to handle the responsibility. He was of the view that there was urgent need to revisit the FDI Policy. It was argued that the domestic drug sector developed over 35 years was far too important to be sold

to MNCs. FDI should be capped with graded fiscal and regulatory incentives based on transfer of technology and actual production in India. Restrictions on the sale of equity of existing domestic drug companies to foreign entities through appropriate procedures such as FIPB should be incorporated. The marketing approval for new patented drugs should be conditional to manufacture within the country in a time bound schedule. He concluded his presentation by citing an observation made by the Department Related Parliamentary Standing Committee on Health in its 45th Report which underlined an urgent need for policy option to ensure that major Indian pharma companies remain in Indian hands.

12. Mr. Aamir Khan mentioned that his team was not entirely opposed to FDI in Phama. FDI should be capped at 49% and should be in a regulated form so that the management and advantage remained with Indian companies.

13. Thereafter, Dr. Samit Sharma submitted his views on generics, prescription and drug pricing. He mentioned that the Government of India implemented a series of policy measure in the 1970s to achieve self-sufficiency in pharmaceutical production which included the Patents Act 1970 that allowed only process patent protection and made possible the production and sale of new medicines at affordable prices. Also, the policies like direct price control on all formulations of about 347 bulk drugs, production of bulk drugs in public sector, control measure on foreign ownership under which foreign companies were not allowed to hold more than 50% of equity forced the MNCs to start production of both formulation and bulk drugs in India. He stated that India has maximum number of production units in the world. Out of these 750 companies are WHO-GMP approved and 74 manufacturers are US-FDA approved which is second only to USA. He submitted that India is rightly called the generic capital of the world as it not only catered to the domestic demand but also the international needs exporting around 50 per cent of the total value of the industry. UNICEF, IDA and many other international agencies and even the US Presidents' Emergency Plan for AIDS Relief procure drugs from India.

14. He specified that two major policy decisions of the Indian Government has affected the accessibly and affordability of drugs, changing the scenario of the domestic drug industry. The first being the adoption of Process Patent from 2005 onwards and secondly, liberalization of FDI norms in the pharma sector since 2001 which resulted in 100% FDI in phama sector through automatic route. It was mentioned that brownfield acquisition entails only taking over the management and adds nothing to the nation's drug production capacity. These acquisitions have increased the foreign dominance over the drug industry from 15 per cent to 25 percent within three years. If six more major companies are acquired then more than 50 per cent of the domestic industry will be dominated by the foreign MNCs making us substantially dependent upon them. He opined that dangers of imperialism were inherent in these acquisitions. Citing the example of anti-cancer drug Sorafenib Tosylate which was being sold by a German company for Rs. 2,80,000 for a packet but when India issued its first Compulsory Licence (CL) on application of an Indian generic drug manufacturing company Natco to produce and sell the medicine for Rs.8,800. He submitted that if companies like Natco are acquired by MNCs, there will be serious dearth of applications for CL and highly priced drugs could not be offered at lower prices. He then provided a few other examples of exorbitantly priced drugs which could be easily replaced by affordable priced drugs. If the intent is good, FDI should be allowed with some restriction.

15. Dr. Sharma shared with the Committee the system of providing generic medicines by the Rajasthan Government. He mentioned that tenders are called and many manufacturers quote the near-tender price. The qualities of these drugs procured are in agreement with quality standards of Drugs and Cosmetics Act, 1940. A surprising thing that surfaced in these transactions is that the company marketing a particular drug at high price offer tender price at one tenth of the price they get in market.

16. He informed that 78% of the prescriptions by the doctors in the USA are by generic names and it is for the patient to decide which company to procure from.

In case the medicine is prescribed by brand name, the doctor has to indicate the reason for prescribing the brand name. Rule 1.5 of the Code of Ethics framed by Indian Medical Council says that doctors should prescribe a particular drug by its generic name as far as possible but this Rule was not being implemented. The weakness of Drugs Price Control Order (DPCO) was also exposed since in real terms price of only 30 out of 74 drugs under Price Control Order are controlled and the rest of the drugs are either obsolete or their ceiling price has not been decided. It was suggested that the prices of drugs needed to be controlled and a proper ceiling price is prescribed for all the drugs.

17. Shri Aamir Khan submitted that the generics should be made available at all Government hospitals because local chemists tend to sell generics at Maximum Retail Price where as it can also be sold at Minimum Retail Price.

18. The Chairman thanked Shri Aamir Khan and his colleagues for their valuable inputs on the subject. He observed that the proceedings of the meeting are confidential and should not be divulged outside till the Report on the subject is presented in the Parliament. The witnesses then withdrew.

19. A verbatim record of the proceedings was kept.

20. The Committee adjourned at 1.17 p.m.

## XXII
## TWENTY SECOND MEETING

The Department Related Parliamentary Standing Committee on Commerce met at 2.00 P.M. on Monday, the 2nd July, 2012 in Committee Room 'C', Ground Floor, Parliament House Annexe, New Delhi.

**PRESENT**

**MEMBERS**

1. Shri Shanta Kumar — *Chairman*

**RAJYA SABHA**

2. Dr. E. M. Sudarsana Natchiappan
3. Shri K. N. Balagopal
4. Shri Prem Chand Gupta
5. Shri Kiranmay Nanda

**LOK SABHA**

6. Shri G.S. Basavaraj
7. Shri C.M. Chang
8. Shri K.P. Dhanapalan
9. Shri Shivarama Gouda
10. Prof. Sk. Saidul Haque
11. Shri Dilip Singh Judev
12. Shri Nalin Kumar Kateel
13. Shri Dayanidhi Maran
14. Shri Vishnu Deo Sai
15. Shri M.I. Shanavas
16. Shri Rajaiah Siricilla
17. Shri K. Sudhakaran
18. Shri Modugula Venu Gopala Reddy
19. Shri K. Jayaprakash Hegde

**SECRETARIAT**

Smt. Sharada Subramaniam, Joint Secretary
Shri J. Sundriyal, Director
Shri Amit Kumar, Assistant Director

**WITNESSES**

**REPRESENTATIVES OF ORGANISATION OF PHARMACEUTICAL PRODUCERS OF INDIA**

Shri Ranjit Shahani, President
Dr. Shailesh Ayyangar, Vice President
Shri Tapan Ray, Director General

2. The meeting commenced with an opening observation by the Chairman where in he welcomed the Members of the Committee and informed them about the agenda of the day.

3. The Chairman then welcomed Shri Rajat Sahani and his colleagues from Organization of Pharmaceutical Producers of India (OPPI) to the meeting of the Committee. He observed that FDI has helped Pharma MNCs acquire stakes in domestic pharma companies or in complete takeover of these companies. He mentioned that various stakeholders have expressed concerns over the mergers and acquisitions in the pharma industry and its impact on the citizen with respect to availability and accessibility to cheap and quality drugs and also on the production of generics in the country. The Chairman also sought the views of OPPI representatives on other issues like the extent of thrust R&D has got over the years on account of FDI in pharma, expansion in the manufacturing capacity of pharma sector and the jobs created therefrom. He also wanted to know the reasons behind the recent spate of takeovers and acquisitions, the social responsibility undertaken by the pharma MNCs in terms of providing cheap generic drugs to people, response of large pharma MNCs to Compulsory Licensing, the quantum of funds invested in R&D of medicines for tropical diseases, new drug, specific to local demands, made by the pharma MNCs during these years, the pattern and share of exports of pharma MNCs during last five years and increase in price of medicines due to recent acquisitions.

4. Shri Ranjit Sahani, President, OPPI thanked the Chairman for giving OPPI the opportunity to present its views to the Committee. He first introduced his colleagues to the Committee and then gave a brief introduction of OPPI.

5. Thereafter, Mr. Tapan Ray, Director General made a power point presentation. He informed the Committee that India stood 6$^{th}$ in terms of pharma market size globally. To him, the FDI was a positive contributor to India's health and economic development and has aided in creation of high-tech processes, international best practices and stimulated growth in Research and Development and manufacturing through technology co-operation. He informed that FDI has expanded product lines and increased export opportunities for local pharma companies through greater access to foreign markets.

6. Dwelling upon the reasons for India becoming an attractive destination for FDI in pharma sector, he figured huge domestic market size and steady growth, cheaper operating cost, English-speaking skilled manpower, efficient and transparent regulatory system, robust healthcare system, including healthcare financing and infrastructure, efficient IT infrastructure, effective legal and IPR framework and predictability in business environment as the key drivers that attracted FDI into the country. He then provided details of the Mergers and Acquisitions and collaborative deals that have taken place in the pharma industry from 2006-11. He also shared with the Committee the strides taken by Indian pharma companies in the global arena. According to him the apprehensions that FDI in pharma would lead to oligopolistic market and lessen the competition leading to escalation in the prices were unfounded and at the same time there was no fear of curtailment of the power of the Government to grant Compulsory Licences.

7. Elaborating about the structure of the Indian pharma industry, he mentioned that it was highly fragmented as there are over 23,000 players and 60,000 brands. He submitted that in a scenario like this, the apprehension of an 'oligopolistic market' being created through acquisitions/ takeovers by MNCs doesn't hold

ground. He argued that the idea of creating a legal barrier by fixing a cap on FDI flow just from the compulsory licence point of view was unreasonable and tantamounts to protectionism in this globalized world. He stated that the market competition was extremely fierce in India since each branded generic/ generic drug has no less than 50 to 60 competitors within the same salt. He also argued against the fear that acquisition of Indian drug companies by MNCs would lessen the competition and hurt the consumer interest was highly imaginary. He submitted that safeguards in the form of Competition Commission of India and National Pharmaceutical Pricing Authority were in place to arrest price rise of essential drugs and anti-competition practices, if any. Concluding the presentation, the Director General stated that in view of the positive development of India's health and economy limiting FDI in pharma industry would be a retrograde step.

8. After hearing the presentation of the witnesses, the following concerns/ issues were raised by the Members of the Committee:-

(i) changes noticed in the structure of pharma industry due to the adoption of product patent and end of the process patent regime which was behind the generic revolution in India;
(ii) doctors prescribing branded and high price medicines when alternative in terms of cheap and quality generic exists;
(iii) preference of patients for branded drug and lack of awareness regarding the efficacy of generic drugs;
(iv) standard of quality of generic drugs manufactured in the country;
(v) effectiveness of the Drug Price Control Order that allows 10% annual increase in the base price of drugs in cases where a medicine introduced already has high base price;
(vi) reasons behind MNCs acquiring domestic pharma companies rather than investing in Greenfield ventures;
(vii) MNC's treatment of Indian companies as authorised producers of generic drugs under patent name leading to reduction in competition;
(viii) huge variation in the prices of branded and generic drugs in spite of both being of same quality and effect;
(ix) difference in the export quality of generic and branded drugs;

(x) reasons behind the Government's decision to permit 100 per cent FDI in pharma industry;

(xi) industrial investment through FDI for carrying out contract manufacturing;

(xii) reasons and status of clinical trials being conducted in India for pentavalent vaccine; and

(xiii) apprehensions that MNCs would come through FDI to conduct trials and clinical tests in India for developing a drug and then manufacture and market it outside the country.

9. The witnesses then responded to the issues/ concerns raised by the Committee. The Chairman thanked the representatives of OPPI for the valuable information on the subject. The witnesses then withdrew.

10. A verbatim record of the proceedings was kept.

11. The Committee adjourned at 3.50 p.m.

## V
## FIFTH MEETING

The Committee met at 12.00 Noon on Friday, the 21st December, 2012 in Room No. '63', First Floor, Parliament House, New Delhi.

**PRESENT**

1. Shri Shanta Kumar — *Chairman*

**RAJYA SABHA**

2. Shri Shadi Lal Batra
3. Shri Rangasayee Ramakrishna
4. Shri K. N. Balagopal

**LOK SABHA**

5. Shri G.S. Basavaraj
6. Shri C.M.Chang
7. Prof. Sk. Saidual Haque
8. Shrimati Putul Kumari
9. Shri Jagdish Sharma
10. Shri Adagooru Vishwanath
11. Shri Nama Nageswar Rao

**SECRETARIAT**

Smt. Sharada Subramaniam, Joint Secretary
Shri J. Sundriyal, Director
Shri Narendra Kumar, Deputy Director

**WITNESSES**

**REPRESENTATIVES OF NATIONAL PHARMACEUTICAL PRICING AUTHORITY**

Shri C.P. Singh, Chairman
Shri A.K. Gautam, Member Secretary
Shri Sanjay Kumar, Member Secretary
Shri R. Asokan, Director
Shri Jagdish Kumar, Director

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* 1st to 5th Meetings of the Committee pertain to other matters.

**REPRESENTATIVES OF DEPARTMENT OF INDUSTRIAL POLICY AND PROMOTION, MINISTRY OF COMMERCE AND INDUSTRY**

Shri Deepak Narain, Director

2. * * *

3. The Chairman then welcomed Shri C.P. Singh, Chairman, National Pharmaceutical Pricing Authority (NPPA), flagged the concerns of the Committee on the subject 'FDI in Pharmaceuticals Sector' and sought his views thereon. The Chairman, NPPA thanked the Committee for giving him an opportunity to express his views on the subject. In his presentation he gave an overview of the pharma industry in India alongwith the mandate and functioning of the NPPA. It was informed that NPPA came into existence in the year 1997 and presently there are 74 medicines and approximately 1,600 formulations which come under the price control mechanism of NPPA. Mechanism being adopted by the NPPA for keeping the prices of the drugs under control was also shared with the Committee.

4. After the presentation of the Chairman, NPPA, the following concerns/ issues were raised by the Members of the Committee:-

(i) average margin between the manufacturing cost and printed cost of medicines;

(ii) mechanism followed for keeping the prices of drugs under control;

(iii) effect of FDI and acquisition of domestic pharma companies by the MNCs;

(iv) criteria adopted to fix the prices of medicines;

(v) mechanism to deal with the unfair trade practices noticed in the pricing of drugs;

(vi) turnover of scheduled and non-scheduled drugs in terms of percentage;

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*** Pertains to other matters

(vii) Any provision for having a cost plus profit price for drugs;

(viii) efficacy of the Authority in ensuing affordable health care in the country through control of price of medicines; and

(ix) Consumer information system whereby information of branded medicines along with its basic formulation/generic version could be obtained.

5. The Chairman, NPPA replied to the issues raised during the meeting. The Committee desired that a copy of National Pharmaceutical Pricing Authority (NPPA) Study on Indian Drug Companies, Ernst and Young Report on Takeovers of Indian pharma companies by Multi National Companies (MNCs), Global parameters applied to drug pricing and its comparative analysis with the Indian method of drug pricing and National Pharmaceuticals Pricing Policy, 2012 may be obtained from the National Pharmaceutical Pricing Authority (NPPA). The Chairman thanked the representatives of NPPA for the information provided to the Committee.

*(The witnesses then withdrew)*

6. The Committee, then, took up the review of the progress made by it on the subject 'FDI in Pharmaceutical Sector'. Some Members were of the view that before the final evidence of Secretaries of concerned Departments, it would be better to visit to few pharma companies for interactions with stakeholders including state drug controllers to better appreciate the situation prevailing on ground. * * *.

7. A verbatim record of the proceedings was kept.

8. The Committee then adjourned at 1.55 p.m. to meet again on 7th and 8th January, 2013.

## *VIII
## EIGHTH MEETING

The Committee met at 3.00 P.M. on Monday, the 21st January, 2013 in Committee Room 'A', Ground Floor, Parliament House Annexe, New Delhi.

**PRESENT**

1. Shri Shanta Kumar — *Chairman*

**RAJYA SABHA**

2. Shri Vijay Jawaharla Darda
3. Shri Shadi Lal Batra
4. Shri P. Bhattacharya
5. Shri Rangasayee Ramakrishna
6. Shri Ishwarlal Shankarlal Jain

**LOK SABHA**

7. Shri G.S. Basavaraj
8. Shri Jayant Chaudhary
9. Shri K.P. Dhanapalan
10. Shri Shivaram Gouda
11. Prof. Sk. Saidul Haque
12. Shri P. Lingam
13. Shri Arun Yadav

**SECRETARIAT**

Smt. Sharada Subramaniam, Joint Secretary
Shri J. Sundriyal, Director
Shri Narendra Kumar, Deputy Director
Shri Amit Kumar, Assistant Director

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* 6th and 7th Meetings of the Committee pertain to other matters.

**WITNESSES**

**REPRESENTATIVES OF DEPARTMENT OF HEALTH AND FAMILY WELFARE, MINISTRY OF HEALTH AND FAMILY WELFARE**

1. Shri P.K. Pradhan, Secretary
2. Shri R.K. Jain, AS & DG, CGHS
3. Shri Arun Kr. Panda, Joint Secretary
4. Shri G.N. Singh, DCG (I)

**REPRESENTATIVES OF DEPARTMENT OF ECONOMIC AFFAIRS, MINISTRY OF FINANCE**

1. Shri Shaktikanta Das, Additional Secretary
2. Shri P.K. Misra, Joint Secretary
3. Shri P.K. Bagga, OSD (CM&Inv)

2. At the outset, the Chairman welcomed the Members of the Committee and apprised them about the agenda of the meeting. He informed the Members that Secretary, Department of Economic Affairs who was scheduled to appear before the Committee had requested in writing exemption from personal appearance and requested to allow Additional Secretary of the Department to appear before the Committee and acceded to his request in view of his official pre-occupation. Thereafter, he welcomed Shri P.K. Pradhan, Secretary, Ministry of Health and Family Welfare and Shri Shaktikanta Das, Additional Secretary, Department of Economic Affairs and their colleagues to the meeting. Initiating the discussion, the Chairman shared the concerns of the Committee regarding the effects of FDI in Pharmaceuticals that may prove detrimental to public health in terms of availability, affordability and accessibility of medicines. He sought to know whether the present FDI policy in the pharma sector has any bearing on the availability of cheap and quality generic drugs and increased dependence on costly imported drugs. He further sought to know the extent to which the FIPB ensures that Brownfield proposals so cleared do not have adverse impact on the public

health. The Chairman enquired whether it was feasible to insert sectoral specific clause in the Competition Act, 2002 authorizing the Competition Commission of India (CCI) to vet FDI proposals in Pharmaceuticals Sector and issue directions in that matter. He sought the response of the Department of Health and Family Welfare in the recently notified National Pharmaceutical Pricing Policy, 2012 in context of the takeovers, and the tangible effects of FDI in Pharmaceuticals Sector on the public health care delivery program of the country. The Chairman also expressed concerns over the growing trend of clinical trials of drugs in the country. The Chairman wanted the representatives of Department of Economic Affairs to explain the approval mechanism devised in FIPB including the monitoring of FDI proposals and the extent of interaction with the Department with the Ministry of Health and Family Welfare and Department of Pharmaceuticals under the broad parameters of availability, accessibility and affordability of drugs by poorer section of society and the FDI Policy in the context of manufacturing and R&D facilities particularly after acquisition of Indian drug manufacturers by foreign multi national companies.

3. Secretary, Ministry of Health and Family Welfare first gave a brief overview of the health scenario of the country. He stated that the healthcare in India has a mix of public and private stakeholders. While the State Governments supply drugs at all primary health facilities and the Centre provides support under the National Rural Health Mission. The Centre also supplies some of the drugs directly for communicable diseases like TB, malaria, leprosy, etc. and for maternal health like folic acid, vitamin A syrup, etc. He informed that States like Tamil Nadu and Rajasthan had started very large-scale supply of generic drugs in all public health facilities and the Centre has advised all the State Governments to follow the example. He further informed the Committee that the 12$^{th}$ Plan envisages supply of free generic drugs to all those who access health facilities.

4. As regard FDI in Pharmaceuticals Sector, the Health Secretary stated that when FDI was introduced in the Pharma Sector in the automatic route, it was

perceived that both Greenfield Projects as well as Brownfield Projects would attract FDI but it did not happen so. Rather seven major Indian pharmaceutical companies have been acquired by MNCs and only one Greenfield Project has come up in Hyderabad since 2001. This led to review of FDI policy under the automatic route. In November 2010, the Health Ministry wrote to the DIPP that the FDI policy should be revisited and the public health concerns should be attended to. After several rounds of discussions, it was decided that 100% FDI through automatic route would be allowed in Greenfield Companies and 100% FDI through Government approval route in Brownfield Companies and accordingly DIPP issued the revised guidelines.

5. The Secretary elaborated that an internal committee was set up under the chairmanship of the Additional Secretary, DEA to look into the aspect of FDI in Brownfield Pharma projects. The Ministry of Health raised several concerns with the committee and suggested whenever a proposal for Brownfield Project in pharma sector is taken up for consideration, it must be ensured that the company receiving FDI should continue to produce medicines under the extant NLEM for the domestic tariff areas at the level which would be the highest quantity of production in the previous three financial years for the next five years. Such company would also be required to maintain the R&D expenditure at the maximum level incurred in any of the three financial years immediately preceding the year of induction of FDI for the next five years. The third condition mandated complete information about transfer of technology to administrative Ministry and FIPB. The internal committee agreed to all the three stipulations. On the issue of clinical trials, he informed that with a view to streamline the procedure for according approval for clinical trials and subsequent monitoring, the Ministry had constituted 12 technical advisory groups to go into subjects and only after their detailed examination, the approval for clinical trials was given. The Health Ministry also propose to amend the Drugs and Cosmetics Act to streamline the

procedures for clinical trials, for more checks and balances and more oversight to the entire process of clinical trials.

6. Thereafter Additional Secretary, Department of Economic Affairs briefed the Committee about FIPB and its functioning. He concurred the views of Health Secretary on about the working of the Inter Ministerial Working Group about the conditionalities to ensure the public health concerns while allowing FDI in brownfield projects. He informed the Committee that between November 2011 and December 2012, of the total 48 proposals taken up for consideration, 45 proposals have been approved aggregating to an investment of Rs.6924 crores in consultation with the other Ministries. Deliberating on the mandate of Competition Commission of India(CCI) he clarified that assessment of CCI to a proposed merger or acquisition is independent of the source of investment-whether the source of investment is from FDI or from a domestic source. He submitted that Government has asked the Ministry of Corporate Affairs to examine whether CCI can impose conditionalities on mergers and acqusitions and come out with recommendations in this regard.

7. After hearing the preliminary presentation of the witnesses, the following concerns/ issues were raised by the Members of the Committee:-

i) the effect on Small Scale Industries after allowing 100% FDI in pharma sector;

ii) mechanisms to supervise the clinical trials being undertaken by pharma MNCs;

iii) the share of investment in R&D by private pharma companies;

iv) efficacy of monitoring mechanism on the R&D investments by pharma companies;

v) methods to encourage MNCs to focus their R&D ventures on India specific diseases;

vi) structural imbalances present in the government and lack of co-ordination amongst various Departments and even at State-Centre Level;

vii) cases where pharma companies have been regulated to bring down the prices of medicines and the details there of;

viii) the details of growth rate of foreign investment from 2007 to 2013 and growth rate of profit of MNCs in the same period;

ix) efforts made by the Government to ensure availability of generic drugs and prescription of generic drugs by doctors;

x) reasons behind shifting from cost based pricing to market based pricing under the National Pharma Pricing Policy, 2012;

xi) steps taken by the Government to ensure that costly medicines are made within the reach of common man with the use of compulsory licensing;

xii) the effect of FDI on the supply and pricing of essential medicines;

xiii) production of essential medicines at affordable rates by acquired companies and the mechanism of pricing adopted by them;

xiv) need of a regulatory mechanism over pricing and supply of medicines;

xv) the effect of change in the patent regime and the FDI policy on the prices of drugs; and

xvi) role of CCI in ensuring that there is no monopoly kind of situation in the pharma due to take overs and the pricing mechanism is not hijacked by the MNCs investing in the Indian pharma market.

8. The witnesses gave clarifications on the issues raised. The Chairman, then, thanked the witnesses for the information provided.

*(The witnesses then withdrew)*

9. A copy of the verbatim record of the proceedings was kept. The Committee adjourned at 04.31 p.m.

## *X
## TENTH MEETING

The Committee met at 3.00 P.M. on Wednesday, the 13th March, 2013 in Committee Room 'A', Ground Floor, Parliament House Annexe, New Delhi.

**PRESENT**

1. Shri Shanta Kumar — *Chairman*

**RAJYA SABHA**

2. Shri Shadi Lal Batra
3. Shri P. Bhattacharya
4. Shri Rangasayee Ramakrishna
5. Shri K.N. Balagopal
6. Shri Ishwarlal Shankarlal Jain
7. Shri Birendra Prasad Baishya

**LOK SABHA**

8. Shri K.P. Dhanapalan
9. Shri Shivaram Gouda
10. Prof. Sk. Saidul Haque
11. Smt. Putul Kumari
12. Shri Arun Yadav
13. Shri Nalin Kumar Kateel
14. Shri Nama Nageswar Rao

**SECRETARIAT**

Smt. Sharada Subramaniam, Joint Secretary
Shri J. Sundriyal, Director
Shri Narendra Kumar, Deputy Director
Shri Amit Kumar, Assistant Director

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* 9th Meeting of the Committee pertains to other matters.

**WITNESSES**

**REPRESENTATIVES OF DEPARTMENT OF INDUSTRIAL POLICY AND PROMOTION, MINISTRY OF COMMERCE AND INDUSTRY**

1. Shri Saurabh Chandra, Secretary
2. Shri Vijay Shankar Madan, AS&FA
3. Ms. Anjali Prasad, Joint Secretary
4. Shri D.V. Prasad, Joint Secretary

**REPRESENTATIVES OF DEPARTMENT OF PHARMACEUTICALS, MINISTRY OF CHEMICALS AND FERTILISERS**

1. Shri Dilsher Singh Kalha, Secretary
2. Shri C.P. Singh, Chairman, NPPA
3. Shri Shambhu Kallolikar, Joint Secretary
4. Shri Pradeep Yadav, Joint Secretary
5. Shri Sanjay Kumar, Member Secretary

2. The Chairman welcomed the Members to the meeting of the Committee and informed them about the agenda. Thereafter, he welcomed Secretary, Department of Pharmaceuticals and Secretary, Department of Industrial Policy and Promotion. The Chairman conveyed Committee's concerns over the likely adverse impact of FDI in pharmaceuticals sector on the availability, affordability and accessibility of medicines to people at large and its detrimental effect on public health. He also expressed concerns over the fact that brownfield investments have outnumbered greenfield investment. He sought to know the preparedness of Government to address these concerns and also the efficacies of bringing down the slab of FDI to less than 50 per cent in case of brownfield projects.

3. Secretary, Department of Industrial Policy and Promotion, Ministry of Commerce and Industry began his deposition with a power point presentation covering different aspects of the pharmaceutical sector in India, FDI Policy of the Government, FDI equity inflows in the sector, major acquisition and takeovers and their impact on the Indian pharma sector Maira Committee's recommendations,

findings of the study conducted by M/s Ernst & Young, provisions for compulsory licensing etc. The Secretary informed the Committee that India commands the third rank globally in volume of production and fourteenth in terms of monetary value. He submitted that prior to the year 2001, FDI in pharmaceuticals was subject to sectoral caps and it was only in 2001, 100 per cent FDI was permitted under the automatic route for the pharmaceutical sector. The Committee was informed that till 2012-13 (April-December) the total FDI inflow has been to the tune of Rs. 45,980.03 crore.

4. The Secretary then shared in brief the general apprehensions about adverse impact of merger and acquisition in the area of (i) production of generic drugs; (ii) availability of life saving drugs; (iii) compulsory licence for production of drugs in case of epidemic/medical emergency; and (iv) production capacity of drugs likely to go off patent in 2012 & 2013.

5. The Secretary also apprised the Committee about the recommendations of the Maira Committee requiring greenfield investments and the comparative instrumentality of Competition Commission of India (CCI) vis-à-vis Foreign Investment Promotion Board (FIPB) for scrutiny of acquisition proposals in the pharmaceutical sector. Recommendations of the Ernst & Young Study were also shared with the Committee.

6. The Committee was informed that a total number of 45 FDI approvals amounting to about Rs. 6400 crore have been granted by the FIPB and FDI equity inflows between November, 2011- December, 2012 have been to the tune of about Rs. 3855 crore. On being asked about the separate record for greenfield and brownfield inflow, the Committee was informed that RBI data on FDI equity inflows does not distinguish between greenfield and brownfield investments.

7. As regards the impact of TRIPS obligation on domestic generic drugs production, it was submitted that India signed the TRIPS Agreement in the year 1994 and as per the agreement it is obligatory on all member States to accord equal treatment to nationals of other member States with regard to the protection of

intellectual property. It was added that the necessary amendments were made in the domestic IPR legislation in order to harmonize Indian IPR regime with the TRIPS Agreement. The Committee was also apprised about the provisions for compulsory licensing.

8. Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilisers informed the Committee that FDI in pharmaceutical sector is different from FDI in any other sector on account of its direct connection with the health sector of the country in general and health of people in particular. He submitted that FDI in pharma sector is more sensitive carrying larger public interest than any other FDI policies of the country. He informed that till 2012-13 the country has received investments to the tune of Rs. 40,000 crore approximately in pharma sector whereas the Indian pharma companies have invested about Rs. 22,000 crore in other countries.

9. On the issue of FDI equity inflow resulting into takeovers/mergers, it was clarified that as per the evidences available till date there has been no deceleration in the production either by a company or in any particular product. Further, on the issue of monopolising the Indian markets by the pharma MNCs, it was informed that the takeovers/mergers have not led to monopoly of foreign pharma companies. The Secretary, however, did not rule out the possibility of monopoly of big companies on account of big mergers in the future. To him the increase in the prices of drugs was mainly attributed in the higher rate of inflation and not on account of these mergers/takeovers.

10. Secretary, Department of Pharmaceuticals conceded that the state of public health in the country is not satisfactory. He emphasised that in order to increase the reach of public health services, the Government needs to invest on its own in the health sector. He also was of the view that cheap and affordable medicines can be made available to the public, only through public health programs and Government procurement and supply and not by restricting FDI alone. He opined that the remedies to affordable medicines and healthcare lie in programmes like

National Rural Health Mission and other Government interventions and not in blocking FDI in pharma. According to him our FDI policy in pharma should be robust enough and be armed with powers to intervene and stop the negative impacts on public health.

11. On the drug pricing Policy front, he submitted that the landed price of imported medicines which was earlier not controlled by any domestic policy, is now under the purview of the New Pharma Pricing Policy where the ceiling price of domestically produced medicines and imported medicines would be pegged at the same level. He informed the Committee that the present provision would help in checking the lacuna of the old policy and promote the domestic industry. As for the present status of the NPP Policy, he assured the Committee that the Department will try to notify it by April after the due process.

12. After the presentation, the members raised queries and sought clarifications on the following issues:

(i) use of Compulsory Licensing to ensure availability of highly priced drugs within the reach of the common man;

(ii) adherence of Compulsory Licensing by private companies;

(iii) maintenance of exact number of greenfield investments and brownfield investments so as to get a clear picture as to which side the investments are tilted;

(iv) Compulsory Licensing vis-à-vis R&D issues;

(v) harmonization of the functions of FIPB and CCI;

(vi) need to review the clearances required to start a pharma unit;

(vii) investments by Indian pharma companies abroad and the issues connected therewith;

(viii) issues relating to prices of drugs produced by foreign companies, dumping and controls on the pricing of non-scheduled drugs; and

(ix) status of bulk drug production post 100 per cent FDI in the pharma sector

13. The witnesses gave clarifications on the issues raised. The Chairman, then, thanked the witnesses for the inputs provided on the subject.

*(The witnesses then withdrew)*

14. A verbatim record of the proceedings was kept.

15. The Committee then adjourned at 04.50 p.m.

## *XV
## FIFTEENTH MEETING

The Department Related Parliamentary Standing Committee on Commerce met at 3.00 P.M. on Monday, the 20th May, 2013 in Committee Room 'E', Basement, Parliament House Annexe, New Delhi.

**PRESENT**

**MEMBERS**

1. Shri Shanta Kumar — *Chairman*

**RAJYA SABHA**

2. Shri Vijay Jawaharlal Darda
3. Shri Shadi Lal Batra
4. Shri Rangasayee Ramakrishna
5. Shri K. N. Balagopal
6. Shri Prem Chand Gupta

**LOK SABHA**

7. Shri G. S. Basavaraj
8. Shri C. M. Chang
9. Shri K.P. Dhanapalan
10. Prof. Sk. Saidul Haque
11. Shri P. Lingam
12. Shri Vishnu Dev Sai
13. Shri Jagdish Sharma
14. Shri Nama Nageswar Rao

**SECRETARIAT**

Shri J. Sundriyal, Director
Shri Narendra Kumar, Deputy Director
Shri Amit Kumar, Assistant Director

2. The Chairman first welcomed the Members to the meeting of the Committee and informed them about the agenda of the day. ***. The Committee then considered the draft 110th Report on FDI in Pharmaceutical Sector. After deliberation the members gave few suggestions for incorporation in the report. The Committee decided to adopt the Report on some later date.

3. * * *

4. The Committee then adjourned at 4.00 p.m. to meet again at 11.00 A.M. on 21st May, 2013.

*** Pertains to other matters

## *XXII
## TWENTY SECOND MEETING

The Department Related Parliamentary Standing Committee on Commerce met at 11.00 A.M. on Wednesday, the 10th July, 2013 in 'Main' Committee Room, Ground Floor, Parliament House Annexe, New Delhi.

**PRESENT**

**MEMBERS**

1. Shri Shanta Kumar — *Chairman*

**RAJYA SABHA**

2. Shri Shadi Lal Batra
3. Shri Rangasayee Ramakrishna
4. Shri Ishwarlal Shankarlal Jain
5. Shri Prem Chand Gupta

**LOK SABHA**

6. Shri G. S. Basavaraj
7. Shri K. P. Dhanapalan
8. Shri Shivaram Gouda
9. Shri Jagdish Sharma
10. Shri Nalin Kumar Kateel

**SECRETARIAT**

Smt. Sharada Subramaniam, Joint Secretary
Shri J. Sundriyal, Director
Shri Narendra Kumar, Deputy Director
Shri Amit Kumar, Assistant Director

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* 15th to 21st Meetings of the Committee pertain to other matters.

2. The Committee took up further consideration of draft 110th Report on FDI in Pharmaceutical Sector on which the Members had suggested changes in its earlier meeting held on 20th May, 2013. After detailed discussion, the Committee adopted the Report with some minor modifications. The Committee then authorised the Chairman to incorporate the modifications suggested by the Committee and finalise the draft 110th Report. The Committee thereafter decided to present/lay *** and the 110th Report on 'FDI in Pharmaceutical Sector' at the earliest opportunity in the ensuing Session of Parliament.

3. The Committee then adjourned at 12.30 p.m.

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*** Pertains to other matters