High Level Committee Report on FDI in Existing Indian Pharma Companies

(ARUN MAIRA COMMITTEE)

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ARUN MAIRA COMMITTEE REPORT - 2011.

AFFORDABLE, ACCESSIBLE, ACCEPTABLE MEDICINES FOR ALL
Issues regarding FDI Policy in pharma sector

The challenge before us

Indian citizens, especially the less well off, need much better healthcare than they are getting presently. Primary, secondary, and tertiary healthcare, as also public health services, must be improved considerably. The Government has given the health sector very high priority in the Approach to the 12th Five Year Plan approved by the Cabinet. Action is required on many fronts, including affordable health insurance, and more hospitals, doctors and para-medical staff. Government must also ensure that the right medicines are available in the country and that they are affordable and accessible even to the poor. There is a system of fixing prices of essential drugs in place in the country which needs to be strengthened further. Free of cost essential drugs are accessible to the population through the primary care system and through several disease control programs for TB, malaria and others etc. and for preventive products like vaccines through immunization programs. These measures, important as they are, leave wide gaps in access to drugs for many common and significant diseases.

India has so far done better than other countries in providing affordable, generic, medicines to its citizens. This was a result of the contrarian approach that India had taken in the 1970s towards intellectual property management in the pharma industry to encourage process patents rather than product patents. This did have favorable impact on R&D innovation based on process simplification with reduced cost. However, while keeping drug prices low, this approach did not provide sufficient incentives for the substantial investments and risks in developing new molecules. Moreover, as India joined the global trade regime since the 1990s, its approach to intellectual property had to conform to the international principles. Thus India joined TRIPS and expects thereby to have easier access for Indian citizens to innovative medicines developed elsewhere, as well as to stimulate more innovations within India. This is important for a long term perspective and to gain experience and expertise in drug discovery and innovation.

There is a growing body of historical evidence that the introduction into other countries of the IPR principles and regime underlying TRIPS, emanating mostly from the USA whose 'innovative' pharma companies have been strong advocates and beneficiaries of this regime, has resulted in the prices of medicines going up in these countries too. Issues of affordability and access to drugs are a universal concern but clearly more critical for us. Therefore, a valid case is made for India not to succumb to pressure from these pharma companies and Western governments, to go beyond the IPR agreements it has already entered into. Presently we are under pressure to concede on date exclusivity, 'evergreening', clause 3(d), which we should not.

The cost of developing innovative medicines is going up internationally. Trial processes for medicines before they can be certified for public use must be much more rigorous than for other products because the products of the drug industry involve the bodies and lives of people. Hence ethical and safety issues must be taken much more seriously than

for other products. There is pressure from Western 'innovative' pharma companies for changes in rules to extend their monopolies on products so that they can recover their increasing costs of drug development. However, as mentioned before, these pressures must not be yielded to because they will result in increases in prices which Indians cannot afford to pay.

Innovative pharma companies cannot substantially increase prices readily in their home markets. Public and governmental pressure on them to reduce prices is increasing with the widespread concern about increasing healthcare costs even in richer countries. Markets for drugs in the West are large but they are not growing as fast as growth in demand for medicines in China, India, and other developing markets where there are large and as yet unmet needs for healthcare and medicines. Therefore almost every Western (including Japanese) company is working on strategies to enter and grow in these markets. The attraction of the growth in emerging markets is not unique to companies in the pharma industry. Foreign companies in almost all industries—automobiles, retailing, telecom, etc—have strategies to enter and grow in India and other emerging markets. We should take advantage of this attraction of our market to bring in technologies and investments that will accelerate the development and growth of our country, expand our innovation experience and expertise and improve the conditions of our people.

However we must ensure that the influx of foreign companies improves the condition of industry in India and provides benefits to Indian citizens. While companies will develop strategies to suit themselves, we must ensure that their strategies do not result in acquisition of power by them to distort competition, and the pricing and availability of medicines in India. Therefore the Indian Government must have the ability to evaluate any major moves by foreign companies into India that could create adverse conditions for Indian consumers. This is the genesis of the recent alarm, rightly raised by the Ministry of Health, about the recent acquisitions of Indian pharma companies by large foreign MNCs.

Government notified a Committee under the Chairmanship of Member (Industry) in the Planning Commission, on June 30, 2011 to examine this matter and give its recommendations by 30th September 2011, with the following terms of reference:

a) Examine whether changes in the structure of the Indian Pharmaceutical Industry by acquisitions of the Indian companies by foreign companies can have deleterious effect by reducing competition in the Indian market that could result in:
    1) increase in price levels of pharmaceuticals in India
    2) less innovation of low cost pharmaceuticals for treating diseases affecting the poor in India.

b) Examine whether acquisition by foreign companies will impact availability of pharmaceuticals in India and increase its dependence on imports

c) Examine whether restraints in the flow of FDI for the purpose of acquisition of Indian Pharmaceutical Companies will unduly constrain the financial resources required for drug discoveries, keeping in mind the large investments are required to develop pharmaceuticals for diseases, including those affecting the poor in India.

d) Consider whether other policies are needed to strengthen the Indian pharmaceutical sector, so as to ensure a vibrant, competitive and innovative Indian Pharmaceutical sector, as also recommend measures for creating an environment conducive for promotion of greenfield investments in the sector and positioning Indian as the leading quality drug research, development and manufacturing destination.

The composition of the Committee is given in **Annexure 1.** The Committee has met three times. It met with representatives of the following associations: Organisation of Pharmaceuticals Producers of India, Indian Pharmaceutical Alliance, Indian Drug Manufactures Association, Association of Biotechnology Enterprises and Competition Commission of India.

It also received written submissions from some of these associations, as well as clarifications following the discussions. It met other experts and a workshop was conducted by the Department of Biotechnology in collaboration with experts from ISB Hyderabad to understand the systemic issues of healthcare which impinge upon the pharma industry. Extensive discussions were held with the Competition Commission too.

The Committee was given some data by the associations to support their generally opposite views on the possibility that, with their larger presence in India, MNCs will cause prices of medicines to go up and will reduce availability of generics in the market. Overall, the data was both insufficient and contradictory and therefore can not be relied upon by itself to allow firm conclusions about likely events in the future. The Department of Pharmaceuticals has analysed data regarding prices and availability of medicines over the past few years and also exports and imports. Its analysis is in **Annexure-2**. The data does not substantiate that acquisitions so far have led to stoppage of nationally relevant drugs. Also a relationship between acquisition and increase in prices is not seen. It is of course to be recognized that acquisitions are recent and more definitive trends will become evident over time.

The Committee considered the views expressed by some that there may be a concerted strategy by foreign companies to take over the Indian drug industry and divert its capacity towards Western markets thus depriving Indian consumers of low cost medicines. On the other hand there was a well substantiated view that MNCs recognize that the future growth in the global drug market will be far more in countries such as China, India, and other developing countries, and therefore their strategies are to enter and sell more in these markets. The attractiveness of the local market will grow substantially with social and economic progress and inevitable increase in public expenditure on health. India is also seen as an attractive base for manufacturing of generics for exports both by

multinational and Indian companies. Acquisition of other companies already established in the market is a universal business strategy in all industries and in all countries, to save time and also ensure more surety of success. Therefore the recent acquisitions of Indian pharma companies by MNCs could as well be an expression, as some evidence suggests, of the strategies of these foreign companies to grow their businesses by investing more in India to produce and sell more in India itself (along with exports from India to other markets). This could be in India's interests, by bringing in more investments and more technologies into our healthcare sector.

The concern, as these investments come in and acquisitions are made, is whether they will alter the structure of the industry within India in a way that Indian consumer interests will be hurt. Data available, as mentioned before, is insufficient to draw any firm conclusions about the future trends. Therefore the Committee went more deeply into the underlying structures of the industry to understand what must be managed by Government to ensure that affordability and accessibility of medicines in India, especially for the poor, is not adversely affected with the advent of more investments into the industry along with the strategic moves of foreign and domestic companies.

Assessment of instruments for Government intervention

The terms of reference of the Committee break down into three basic questions:

- What is the most effective way in which the Indian government can 'control' and regulate the influx of foreign companies into the Indian pharmaceutical market to ensure that there is no detrimental effect of these acquisitions on prices and availability of medicines in India?
- What are the principal actions necessary, in addition to the above, to ensure that medicines are affordable and accessible to all, especially the poor?
- What policies are required to grow a vibrant, competitive, and innovative pharma sector?

The first and most immediate question is: what is the most effective way in which the Indian government can 'control' the influx of foreign companies into the Indian pharmaceutical market to ensure that monopolistic situations do not arise, while foreign investments and technologies are welcomed at the same time. It must also be recognized that monopolistic situations and unreasonable upward pressure on prices can also result from strategies of acquisitions, cartelization, and unfair trade practices of domestic players within the Indian market even if there were no foreign companies. Further, Indian industry itself may diversify investment into other areas as the pressure on drug innovation increases with the growing stringency in regulatory requirements.

Therefore, we must focus on the national objective, which is to ensure affordable and accessible medicines for Indian citizens and look for the best policies and institutional interventions to meet this objective. Hence we must focus on the condition of the market and the structure of the industry as a whole when we assess the effect of any significant move by any company, whether it is a foreign company or Indian. And we must apply an institutional mechanism to handle this issue that is appropriately equipped for it. This

system must be sensitive to public interest, evidence based, supported by strong processes and consistent in its assessment processes and judgements over time. The two possible mechanisms readily available are the FIPB and the recently established Competition Commission.

In the past, until the passage of the Competition Act and creation of the Competition Commission, control of the sizes and structures of companies in an industry, to ensure a healthy structure of the industry, was sought to be managed by administrative decisions of ministries and the FIPB route. This approach had the connotations of the 'license raj' along with the impression of arbitrariness of government decisions. On the other hand, 'competition' management by competition commissions and competition acts, is accepted by even the freest market countries, including the USA as the right approach to regulate activities of players in the market (or entering it) to ensure that the structure of the industry is not distorted against the consumers' interests. If India adopts these instruments of competition management, now available to us, to check the activities of foreign companies in the pharma industry, India cannot be accused of 'going back' on reforms and discouraging foreign investment.

India must take a long term view in selecting the right institutional mechanism for the gatekeeping role. The Committee met officers of the Competition Commission and assessed the preparedness of the Commission to address the issues that are arising with acquisitions of Indian pharma companies by foreign MNCs.

The Committee noted that the Competition Commission of India (CCI) operates within a well defined legal structure, providing legal certainty and transparency to the parties, who have full opportunity to exercise their rights and strong legal protection against any arbitrary decision, with clearly defined appellate processes. In its inquiry into cases of mergers & acquisitions, it takes into account the entire gamut of relevant issues, including those relating to the specific market, interests of consumers, likely impact on prices and availability of relevant products / substitutes, innovation, competitiveness, contribution to economic development etc., and the likely effect of the proposed M&A on competition in the market. The Competition Act, 2002 empowers the Commission to evaluate all aspects of the proposed deal, including those relating to the wide array of concerns deliberated on by the High Level Committee, such as reduction of capacities for production or R&D and market distorting issues related to ownership of IPR. It can reject a proposal or approve it with or without modifications in the final reasoned order, which is required to be delivered within time limits prescribed in the Act / Regulation (30 days for prima facie determination, and 180 days in case further investigation is required). In prescribing the modifications in its order, the Commission can require the parties to make structural changes in either of, or both, the acquiring and acquired entities. Further, the Commission's order can include behavioural / conduct remedies also regarding capacities, IPR issues, etc.

The Competition Commission of India has already designed internal processes for specifically consulting and obtaining requisite data and expert advice from appropriate sources, including the concerned ministries / departments of the government and the

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sectoral regulators, in line with the provisions of the Competition Act, 2002 which duly enable and empower CCI for this purpose. This structure has in-built systems for consultation with designated persons / cells in these organizations. In addition, the CCI could be supported in the health sector by a Standing Advisory Committee to advise on health and pharma issues, thereby providing the CCI with expertise required.

The High Level Committee accepted that the strengths of the Commission were the legal provisions that empower it to assess any proposed acquisitions for adverse impact on competitiveness, consumer interest, and innovation among other issues. However the representatives of the M/o Health expressed concerns that the threshold for action in the Competition Commission would tend to be high, and also that the CCI's capacity, at least in the short run, in the domain areas may be less than optimal. Therefore the Committee including representatives of the Ministry of Health, discussed with the members of the Commission, what could be practical solutions for these two concerns.

1. Sizes of companies/combinations requiring clearance from Competition Commission

As per the present scheme under competition law, the sizes of the target company and the acquiring company together in terms of assets and turnover determine whether an intended 'combination' requires clearance from the Competition Commission. The details of notification threshold are mentioned in **Annexure-3**. Further, only those cases of combinations are required to be notified to the Competition Commission of India where the size of the acquired enterprise in India (the target company) based on turnover is beyond Rs. 750 crore and assets are beyond Rs. 250 crore. These threshold criteria for target companies were introduced vide Notification S.O. 482 (E) dated March 4, 2011 and subsequently amended vide Notification S.O. 1218 (E) dated May 27, 2011. However, it is observed that most pharmaceutical companies in India who are targets of acquisitions at present have turnovers below the threshold introduced for target companies, through above mentioned notifications. Therefore, the Pharma sector would need to be exempted from the operation of these notifications given the importance of this sector for Indian Healthcare requirements. It is expected that this would bring over two thirds of the relevant proposals under purview of the Commission.

As regards the acquiring firm, it is pertinent that most of the combination activities by the multinational firms are being carried out either through their subsidiaries created for this purpose, or through special purpose vehicles, which will have either no or very small turnover as well as small asset base. The threshold criteria under the Competition Act, 2002 are on the higher side. Therefore, most of the acquisitions by multinational corporations of Indian pharmaceutical companies will fall under the category of Group criteria for filing, which at present is USD 3 Billion for assets and USD 9 Billion for turnover on combined basis for the acquired and the acquirer. As per the details available in public domain, the number of Pharmaceutical companies with turnover above USD 9 Billion criteria are limited.

It may be noted that the threshold criteria prescribed in the Act have been increased by 50% vide Notification S.O. 480 (E), dated March 4, 2011. In the case of Pharmaceutical

sector this notification which enhanced the threshold by 50% can be revisited to bring more combination activities under the purview of merger review as per the provisions of the Competition Act, 2002, in order to achieve the objective of adequate scrutiny of the drug industry.

It should be noted that most of the major acquisitions of Indian pharmaceutical companies made so far (Ranbaxy, Wockhardt, Piramal, Vetrex Animal Health) would have required clearances from the Competition Commission, had the provisions relating to combination in the Competition Act, 2002 been made operative when those acquisitions were made. However, the Committee is of the view that since the pharmaceutical industry produces health- related products connected with citizens' fundamental right to life, a much lower level of threshold is warranted in the case of pharmaceuticals. Thereby the companies' strategic moves in the pharma industry can be scrutinized more thoroughly than in other industries.

2. Capacity of the CCI to perform the scrutiny of M&As in the pharmaceutical industry

Specialised knowledge of the industry, along with knowledge of competition management, is necessary to evaluate the consequences of intended M&As on the structure of the pharmaceutical industry and likely effects on prices and innovation in the future. The structure and processes of the CCI enable it to draw in required specialists when required. The Committee noted that, the alternative route, of FIPB also has the limitation that FIPB does not have the requisite special knowledge of the industry. Therefore, on this ground, the CCI is not less capable than FIPB, and may actually be better placed since, as mentioned, CCI has a built-in process for on-boarding specialists as necessary.

The High Level Committee recommends the creation of a Standing Advisory Committee on health and pharmaceutical issues to assist the Commission and ensure adequate capacity. Such a Standing Committee comprising all stakeholders (CCI, ministries / departments, sectoral regulators etc. dealing with various related issues like healthcare, pharmaceuticals, R&D, investment promotion, IPRs), could be constituted to analyze, monitor and address all relevant issues / concerns in a holistic manner. This Standing Committee could be housed in an appropriate organization, perhaps the Ministry of Health, and would function as an ongoing mechanism for regularly monitoring the issues relating to access and affordability of drugs, considering all factors, including anti-consumer practises mentioned later in this report. The Committee would also provide the necessary system level inputs and expert support to CCI, including feedback and advice on the various concerns and possible modalities for addressing them in a systemic manner.

Having considered all the concerns, examined the data, and evaluated the mechanisms available, the Committee's considered view whether there should be some monitoring and control of acquisitions of Indian companies by foreign companies, and what the mechanism for this should be, is as follows:

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1. There was unanimity that there should be monitoring and control of acquisitions to ensure that the structure of the market is not distorted in a way that will be detrimental to the interests of Indian consumers.

2. However there was not unanimity whether the FIPB route or the CCI, should be the mechanism to monitor and control the mergers and acquisitions.

The majority view of the Committee is that the Competition Commission should perform this function, with expansion of the scope of its coverage in the pharma sector as mentioned before and with strengthened capacities by incorporation of a Standing Advisory Committee anchored by M/o Health perhaps. They were of the view that the FIPB route is less well-designed for evidence based decision making than CCI, likely to be less rigorous in its processes, less transparent, and perceived to be less accessible to all stakeholders than CCI. CCI has put in place appropriate institutional structures for open hearings of cases, consultations with experts and stakeholders, as well as time limitations, that will ensure that potential acquisitions are analysed with the Indian citizens' interests fully in mind, while ensuring that the companies involved get fair consideration. Moreover since competition management is a specialized field, the country should use, strengthen, and build the credibility of its institutions for competition management viz the Competition Act, the Commission, and the Appellate Tribunal, rather than reverting to earlier modes of controlling investments by foreign companies. Reversal to those modes may cause concern to foreign investors about the direction of India's economic reforms when the Government is making every effort to attract more foreign investments.

However, Ministry of Health continues to feel that the earlier route of FIPB to control foreign investments is the better one and has requested that its dissenting note be incorporated. It is attached as **Annexure 4.**

It should be noted that if the FIPB route is chosen, CCI clearance will nevertheless be required hereafter even for proposals cleared by the FIPB.

It should be noted also that the Ministry of Health has proposed the FIPB route for brown field investments only, green field investments remaining unimpeded. The CCI route also applies only to M&As, i.e. 'brown field' investments. Green field investments are not affected.

All members of the Committee agreed that green field investments must be attracted. This requires removal of many impediments to investments in new enterprises, such as land acquisition, lengthy government processes, etc. that deter both Indian and foreign investors.

Other policy levers

Attracting more investment to expand and improve production capacities

'Greenfield' investments are clearly the preferred means of foreign investment. To facilitate these, Government must provide systems that can sustain new product innovation by green field companies. There are many hurdles that make investment less attractive in India than elsewhere: difficulties in acquiring land, the hassles of lengthy and complicated government processes to obtain the required permissions to build and establish an enterprise, environmental clearances, etc. One of the key requirements for new drug discovery is world class regulation. Currently, the decision making time is several fold longer than the global best and the capacity to handle new types of drugs other than chemical entities is limited.

These problems make green field investments even more difficult than investments in existing operations. Investments for the expansion and up-gradation of existing facilities will be restricted if FDI is restricted to only green field investments. This will restrict the inflow of funds into the industry and may have the effect of slowing down capacity expansion rather than increasing it. The new Manufacturing Policy developed by the DIPP, under consideration of the Cabinet, is designed to make India more attractive for investments in manufacturing and R&D by foreign companies and Indian companies. The implementation of this Policy must be pursued vigorously to attract more greenfield investments.

We should be careful not to rush into solutions that may solve one problem but could have other consequences, such as an affect on the overall investment flow into the pharmaceutical industry as well as other industries. Therefore we must not lose sight of the overall objective, which is to expand the availability of affordable medicines that are accessible to the poorest people even in remote areas. For this, much more investment is required in many areas, and the entire structure of the industry, including its distribution system, has to be suitably altered. Merely changing the R&D and manufacturing ends of the industry will not result in the required expansion of the market and accessibility of medicines. Poorer citizens' ability to pay will have to be addressed by subsidized health insurance schemes and improving the reach and quality of our flagship health program to address diseases with highest disease burden. Government must also use its market-shaping power by effectively designed bulk purchasing schemes that can induce lower prices from suppliers.

Unlike other industries, Government will have to play a larger role for funding innovations in drug development in view of the human need imperatives coupled with large investments necessary and risks that purely commercial firms have proven generally unwilling to take. This must be coupled with a decisive improvement in support systems for innovation including world class regulation. The potential role of public sector undertakings for production of medicines with latest technologies and new management systems including public-private partnerships needs to be examined.

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IPRs and Compulsory Licensing

Adequate protection of intellectual property rights is required to stimulate investments in innovation and hence India must have a good intellectual property regime in harmony with the basic principles of the international regime. However since intellectual property rights create monopolies to enable inventors to make profits, they can also result in anti-competitive and monopolistic behaviors to the detriment of consumers. As mentioned before, there is evidence that the international norms for intellectual property rights in the pharmaceutical industry may be going too far towards protecting the monopolies of the inventors and hurting consumer interests. Therefore India must not go any further than what it has already committed to under WTO and TRIPs, and not succumb to the pressure being brought on it to yield regarding data exclusivity and modifications to clause 3(d).

TRIPS also provides national governments with the instrument of 'compulsory licensing' to enable them to procure medicines if they are not available in sufficient quantities and at reasonable prices in their countries. In this too, there is some pressure on the Indian government not to exercise its rights (though it has not even done it so far). The Indian Government must retain this right granted to it, and use it if necessary. Thereby it can compel manufacturers in India, whether Indian owned or foreign owned, to compulsorily produce specified medicines when necessary, and thus make those medicines available in India at reasonable prices.

It is also important that the intellectual property generated by publicly funded organizations and those receiving Government support be available for development of low cost drugs in the country.

Drug development environment

One of the key requirements for new drug discovery is world class regulation. We are currently well short of the required standards. There are significant shortfalls in facilities for preclinical phase of drug development, in handling of biologicals by customs and human resource for new drug development. The best in Indian industry has itself highlighted the fundamental weakness in sustaining new drug development by new and non –traditional technologies, and may seek more favorable conditions elsewhere. India must become a favored new drug innovation destination to attract greenfield investments in the prevailing competition for such investments among emerging economies, including China.

The Committee endorsed the need for adequate research to develop drugs that particularly affect Indians and inhabitants of other tropical countries. These include drugs against Tuberculosis, Leishmania and Malaria etc. The development of such drugs needs to be addressed by increased public funding and engagement of the private sector by better incentivisation.

Price controls

Healthcare, as mentioned before, is unlike other industries because it addresses the very fundamental needs of all people, including the miserably poor, to life. Since Government must ensure that all peoples' fundamental needs are provided for, it must use other instruments also, should the conventional instruments of ensuring a healthy structure of the industry and competition fail for some reason to keep prices down and ensure availability of required medicines. For this purpose, selective price control on essential drugs must be used when necessary. Therefore a system is essential for fixing prices of essential drugs such that free of cost essential drugs are accessible to the populations through the entire primary and secondary level health system and through several disease control and preventive immunization programs.

Anti-consumer practices in medicine prescriptions and sales

Customers for medicines are compelled to buy more expensive medicines than they need because there is an asymmetry of information between the prescriber of the product i.e. the doctor, and the anxious patient. Indeed, much of the monopoly power and anti-consumer behavior in the pharma industry is within the prescription and retailing system. Other changes are also required in the distribution system to remove anti competitive practices such as requirement of 'no objection certificates' from trade associations by the stockists etc. Almost all, if not all, pharma companies, whether foreign owned or Indian owned are complicit in this. Therefore systems must be strengthened for monitoring and intervening in the market when necessary to protect consumer interests. In this both the Department of Health and the CCI have roles to play.

The conclusion one must reach is that the ownership of the companies, whether they are Indian or foreign, is not the reason why customers pay more for medicines than they need to. Therefore policies directed to keep one type of owner—foreign or Indian—out of the industry will not result in prices coming down. The solutions required must be structural and apply to all companies in the industry. High level studies have been undertaken recently, especially the recently submitted report by the High Level Expert Group on Universal Health Coverage set up by the Planning Commission to reshape the Indian healthcare sector. These are now feeding into a new national healthcare policy on the anvil. This will clearly include much higher allocations for health care, rapid expansion in the role of the public sector in secondary level health care and additional programs for Chronic Diseases treatment and control and expanded health insurance and health safety networks. Therefore the Committee feels that, rather than it commenting on these broader solutions, the work already underway led by the Health Ministry and Planning Commission must be accelerated.

Plans for a dynamic pharmaceutical industry

To the third question, policies and plans to grow a dynamic pharma industry in India, the Committee noted that the Planning Commission is mid-way into preparing a Plan to achieve the objectives stated in the Manufacturing Policy on the Government's anvil viz. accelerate growth of manufacturing to a rate 2% to 3% faster than the overall economic growth, create more jobs, and increase technological depth and value addition in the country's industries.

The pharmaceutical industry is a priority industry in this plan. Many issues must be addressed to attract more greenfield investments and grow a dynamic pharmaceutical industry. Effective PPP models are required for R&D and production of affordable and new medicines. The growth of MSMEs must be facilitated more effectively. More technically qualified manpower is required. Laboratories, clusters and standards must be improved. The Committee was pleased to note that the Plan, which will be ready within the next three months, will address the policy issues, investments, and other actions required to grow innovation and manufacturing of pharmaceuticals in India.

Business Responsibility

Finally, the Committee would like to make a humble suggestion to all the companies, foreign and Indian, who through their respective associations, represented their views on this contentious issue of whether further ingress by foreign companies into India should be controlled or not. The healthcare and pharmaceutical industries are unlike almost all other industries. The products and services they provide are essentials, even for the poorest persons, related to their human right to life. Generally accepted business management practice may be that companies shall serve only those who can afford to pay what the companies are able and willing to produce. Thus there may be no public resentment against an auto company that does not invent and produce cars for the poorest people; or even no resentment against the auto industry on this account. On the other hand, hospitals who turn away those who cannot afford to pay, and pharma companies that make good profits but do not find ways to service the needs of the most indigent, are not excused by citizenry. Therefore, pharmaceutical companies, whether foreign or Indian, must rethink the broader purpose of their enterprises and their business models to fulfill this broader purpose. This is the arena in which they need innovations most of all—in defining the scope of their business responsibility, the measures of their success, and their business models, not only in discovering innovative medicines.

The future leaders of this industry will be those, foreign or Indian firms, who voluntarily step forward to their responsibility to citizens by providing affordable and accessible medicines to all; who will cooperate with other agencies, in government, academia, and the private sector, in cooperation with whom they can discharge their responsibilities; and who will voluntarily hold themselves up to public scrutiny against measurable targets. Associations of companies must be perceived to not only lobby for the interests of their own members, but more convincingly advocate and work towards the larger public good.

In an era in which businesses are struggling to be seen as 'responsible' so that they can have the trust of citizens and civil society, thereby reducing the pressure from citizens and civil society on government to control business, the pharma industry has the greatest need perhaps amongst industries, to voluntarily become a role model of a new paradigm of business responsibility. Indeed a change in public perception of a company and the association to which it belongs could be a strategic source of competitive advantage in an era of mistrust.

(Arun Maira)
Chairman
High Level Committee to examine the policy
for FDI in existing Indian Pharmaceutical Companies
September 29, 2011

Annexure 1

COMPOSITION OF THE COMMITTEE

1.	Member (Industry), Planning Commission (Shri Arun Maira)	**Chairman**
2.	Secretary, Deptt. of Industrial Policy & Promotion	Member
3.	Secretary, Deptt. of Pharmaceuticals	Member
4.	Secretary, Ministry of Health & Family Welfare	Member
5.	Director General, Council of Scientific & Industrial Research (CSIR)	Member
6.	Secretary, Deptt. of Biotechnology	Member
7.	Chief Economic Adviser, Ministry of Finance	Member
8.	Drug Controller of India	Member

Annexure 2

Trends in Pharma Industry: Data analysis by Department of Pharmaceuticals

1. Escalation in Drug Prices

DoP has conducted a price analysis of the drugs for the period May 2009-2011 as per following categories:

a) **7 top domestic companies**: Cipla, Sun, Mankind, Alkem, Lupin, Zydus Cadilla and Intas

b) **7 top MNCs**: Abbott, GSK, Pfizer, Sanofi Aventis, Novartis, MSD and Merck

c) **7 Major Indian companies acquired by MNCs**: Ranbaxy, Ranbaxy Global CHC, Orchid, Shanta, Paras, Dabur and Piramal.

Above analysis reveals the following –

Category I: Out of a total of 8348 packs, there has been no change in prices for 67.3% of the packs. Only 6.7% packs had price increase up to 5% and 1.8% had price increase more than 15%.

Category II: Out of a total of 3503 packs, there has been no change in prices for 66.7% of the packs. Only 7.6% packs had price increase up to 5% and 5.1% had price increase more than 15%.

Category III: Out of a total of 2035 packs, there has been no change in prices for 70.8% of the packs. Only 6.8% packs had price increase up to 5% and 2.9% had price increase more than 15%.

As regards the general trend of price increase in the domestic market for all companies and all packs as estimated by IMS, it is to be emphasized that out of a total wholesale traded market size of Rs. 48,239 crores comprising 60,498 medicine packs covering 507 pharma companies, the situation in respect of price change is as below.

	2008-09	2009-10	2010-11
% No. of packs whose prices have increased	0.07	1.99	0.09
% No. of packs whose prices have decreased	0.01	1.32	0.06
% No. of packs whose prices are unchanged	99.93	96.69	99.85
% No. of packs whose prices have increased by 20% and fulfilling DPCO criteria*	0.28	0.035	0.03
% No. of packs whose prices have increased by 10% and fulfilling DPCO criteria**	0.84	0.18	0.16
Note:* each year as estimated in the month of April of the year concerned by IMS			

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Conclusion:
Thus it may be seen that the trend in prices for all the three categories is similar so far and no conclusion can be drawn to support the hypothesis that acquisition by MNCs of Indian origin companies has resulted in price increase.

2. Availability of Drugs:

- A trend analysis of the total number of medicine packs available in the domestic market in the last two years shows an increase of 4.3% between March 2009 and March 2010 and 1.4% between March 2010 and March 2011. The overall increase has been 5.8% between March 2009 and March 2011.

- A trend analysis of the total number of new drugs/formulations introduced in the domestic market since May 2009 as per IMS for the 3 categories of companies mentioned in Issue No. 1 above reveals that the total number of new drugs/formulations for each category are –

  a) 1439
  b) 512
  c) 341

Conclusion

Thus there has been increase in the number of medicine packs in the last two years as against perceived decrease in the number of medicines by the Health Department. This is further supported by the fact the number of new drugs /formulations introduced by the 3 categories of companies discussed above.

Specific data may need to be provided by the Health Department in respect of essential medicines or such other medicines which the Health Department deems necessary for national needs. This is important in the context of possible need of compulsory license provision under TRIPS. However, the existing data does not support the proposition that there has been, or there is, a trend towards decreased availability of medicines on account of acquisition of Indian companies by MNCs.

3. Exports and Imports:

As per analysis of export and import data, the year-wise percentage changes in the last 5 years are as below.

	2006-07	2007-08	2008-09	2009-10	2010-11 (P)	CAGR
Exports	20.9%	14.4%	38.6%	6.6%	7.7%	16.5%
Imports	29.9%	14.8%	28.4%	15.2%	8.9%	19.0%

Thus it may be seen that the exports have shown a growth slightly less (about 3%) with respect to the imports and not adversely so to the detriment of the industry. The slowdown in exports is also attributable to the general slowdown in the global economy, particularly in the context of the slowdown being severe in key market segments comprising about 43% - major share of the Indian pharma exports – US (about 24% of Indian pharma exports are to US) and EU (about 19% exports are to EU).

This itself can be attributable to increase from such countries like China, etc., which have a highly uneven based competition with respect to countries like India due to their extant overt and covert support to the manufacturing industry in general bulk drugs industry in particular possibly over and above the WTO Guidelines. In fact in the context of anti-infective therapeutic treatment through antibiotics like Penicillin, DoP has supported the view of DoC-statutory authority for anti-dumping to levy appropriate duty charges on bulk penicillin imports so that while anti-dumping by Chinese exporters is addressed on the one hand, complete dependence on Chinese imports is also taken care of in terms of strategic interests. The matter is pending with the Department of Revenue.

This proposition also seems to be the that increase in exports of pharmaceuticals has taken place at the expense of the domestic market, that is, this is a situation in which any increase in exports will lead to a decrease in availability in domestic markets. This has not been the position of the Indian domestic industry for the last 20 years. In fact the Indian pharmaceutical industry is characterized by a significant increase in both exports as well as the domestic market. It is also a clear-cut objective of the industry, as indicated in the Plan Documents of the Eleventh Plan as well as in the proposed Twelfth Plan; that both exports as well as domestic production are to increase significantly. The export market and the domestic are not in a zero sum situation, and to this extent the increase in exports, if any, by Indian companies acquired by MNCs is something desirable rather than undesirable.

Annexure 3

Competition in the Indian Pharmaceutical Industry

The Indian pharmaceutical industry grew from mere US$0.32 bn (1980) to US $21.26 bn in 2009-10. It ranks 3rd in terms of volume of production (10% of world's production) and 14th in terms of value (1.4%). The Domestic market size is estimated to be worth US$ 12.26 billion. According to IMS Health, on a Moving annual total (MAT) basis, the Indian Pharma market grew at 21.3%. As per projections made by PwC, by 2020, the Indian Pharma industry is slated to grow to US$49 billion with a conservative CAGR of 15% and with the potential to reach US$74 billion at an aggressive CAGR of 20%. (Ref: India Pharma Inc: Capitalising on India's Growth Potential, CII-PwC, 2010).

As of 2009, there were more than 10,000 firms in the market, of which, around 200 collectively controlled about 70% of the market share. Most of the top 10 players in the market had growth rates of over 18% for the 12 months ending July 2010. Of these, Cipla continued to have the largest market share of 5.2%, followed by Ranbaxy (now a subsidiary of Daiichi-Sankyo), with a 4.7% share. This reflects that the market is highly fragmented and even the market leader does not have substantial market share.

Table 1: Top 10 Pharma Players in India (09/10 Revenues in US$ millions)

Company	Revenue
Cipla	1276.1
Ranbaxy	1125.45
Piramal Healthcare*	631.18
Sun Pharma	600.65
GSK India	445.87
Zydus Cadila	436.40
Alkem Labs	276.49
Mankind Pharma	200.06
Pfizer India	192.59
Abbott*	189.07

Source: Business Standard (October 2010), IMS Health, Capitaline as quoted in CII-PwC Report on Pharmaceutical Industry, 2010

*Prior to acquisition

Industry experts believe that this market is largely dominated by branded generics, which account for around 90% of total sales, representing one of the key strengths of the market. About 10% of the market is comprised of commodity generics sold through institutional

sales and innovator products. The branded generics segment is expected to grow at a CAGR of 15% - 20% for the next decade.

Global Pharmaceutical Companies

The global pharmaceutical industry is a multi-billion dollar industry with about 200 major companies. As per the figures available for 2009, based on Global Human Prescription drugs sales, the top 20 players are as follows:

Table 2: Top 20 Pharmaceutical companies in the World

Rank	Company	Sales (in USD Billion)
1	Pfizer	45.4
2	Sanofi-Aventis	42.0
3	Novartis	38.4
4	GlaxoSmithKline	37.8
5	Roche	37.6
6	Astra Zeneca	32.8
7	Merck	25.2
8	Johnson & Johnson	22.5
9	Eli Lilly	21.2
10	Bristol-Myers Squibb	18.8
11	Abbott	15.6
12	Bayer	15.0
13	Boehringer Ingelheim	14.4
14	Amgen	14.4
15	Takeda	14.2
16	Teva	13.9
17	Novo Nordisk	9.8
18	Astellas	9.8
19	Daiichi Sanyo	8.1
20	Otsuka	7.9
Source: Pharmaceutical Executive, May 2010		

Table 3: Threshold criteria for Merger Notification

Group Status	Geographical Coverage	Threshold	
No Group	India	Assets:	Rs.1500 crore ($ 333 mn)
		Turnover:	Rs.4500 crore ($ 1 bn)
	Worldwide	Assets:	US$ 750 million (including at least in India Rs 750 crore)
		Turnover:	US$ 2250 million (including at least in India Rs.2250 crore)
Group	India	Assets:	Rs.6000 crore ($ 1.33 bn)
		Turnover:	Rs.18000 crore ($ 4 bn)
	Worldwide	Assets:	US$ 3 billion (including at least in India Rs 750 crore)
		Turnover:	US$ 9 billion (including at least in India Rs.2250 crore)

As per the provisions of the Competition Act, 2002, only those cases of combinations are required to be notified to the Competition Commission of India where the size of the acquired enterprise based on turnover is beyond Rs. 750 crore ($ 166 mn) and the assets are beyond Rs. 250 crore ($ 55 mn).

From Table 1 given above, it can be observed that with the present threshold criteria for the target companies in India only top 10-12 companies will fall under the prescribed notification criteria. Therefore, the mergers of pharmaceutical companies should be excluded from the ambit of the Notification S.O. 482(E) dated March 4, 2011 and subsequently amended vide Notification S.O. 1218(E) dated May 27, 2011.

Similarly, most of the foreign pharma companies' acquisitions are done either through subsidiaries or special purpose vehicles which have either no turnover or very small. From Table 2, it can be seen that only top 18 companies have turnover beyond the threshold of $9 billion. Therefore, the Notification S.O. 480 (E), dated March 4, 2011 should be modified.

Annexure 4

Views of Ministry of Health & Family Welfare on the Issue of Review of FDI Policy in Existing Pharmaceutical Companies

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The High Level Committee has recognized the need that the Government must have the ability to evaluate strategic moved by Pharma MNCs into India to ensure that availability and affordability of medicines in the country are not adversely affected. The Committee has also underlined the need that a suitable mechanism is desirable for the pharma industry alone as affordable medicines are a public need and directly impact the fundamental right to life of the people of the country. It is also recognized that large investments are required to develop new drugs for diseases including those affecting the poor in the country and that Greenfield investments are clearly the preferred means of foreign investments in this regard.

2. The size of the global pharma industry was estimated in 2009 to be 840 bn US $. 78% of this market amounting to about 590 bn US $ is accounted for by North America, Europe and Japan. During the period 2009-14, these markets are expected to grow at 4-5% annually aggregating to 28 bn US $ which is likely to include relatively low priced generics in view of the growing pressure on the Health budgets of these countries.

3. 100% FDI through automatic route has been in operation in the pharma sector since 2001. However, it is pertinent to note that while during the period August 2006 – December 2010, 7 major takeovers/acquisitions of Indian pharma companies by pharma MNCs have taken place, during the same period, just one case of FDI flow into a green field project has been reported. All these companies have been acquired at highly unrealistic valuations and the sale proceeds thereof have reportedly been diverted to non-pharma Sectors.

4. At present, 28% of the Indian pharma market is controlled by pharma MNCs. If another 3-top Indian companies are acquired, this share will rise to 41%, and further to 55% if another 8-top companies are taken over. This level of dominance by pharma MNCs in the Indian market through acquisitions is likely to have a direct bearing on the product-mix of the acquired companies. This may also lead to increased pressure for introduction

of Data Exclusivity, Patent linkage and evergreening of patents which are beyond the mandate of TRIPs.

5. It should be acknowledged that FDI investment in pharma sector from the public health perspective should address the concerns, namely, (i) it should result in increase in manufacturing capacity; (ii) ensure protection of the pre-eminence of the Indian pharma industry as a global leader in supply of quality and affordable generic drugs; (iii) ensure adequate availability of quality generics for domestic use given the distinct possibility of MNCs changing their product mix in a manner that they supply more of generics at higher prices to the developed markets to the detriment of the domestic market, sell more of their patented products in India and reduce production of generics or delay introduction of new generics; (iv) involve transfer of technology; (v) enhance investments in R&D particularly for diseases relevant for India; (vi) create additional job opportunities and (vii) pharma MNCs should be willing to work out compulsory licensing as and when notified by the Government of India.

6. The main focus of the 12th Plan is to provide affordable healthcare to the people of our country. NRHM is being strengthened and National Urban Health Mission is being launched in this Plan. With the expanded coverage through these programmes and other national disease control programmes and keeping in view the size and population of the country and the urgent need to reduce the level of out of pocket expenditure, requirement of medicines will increase manifold which have to be made available to the people at affordable cost.

7. FDI flow into brown field projects does not address these public health related concerns. Hence, there is a need to scrutinize such proposals. Two instruments, namely, Competition Commission of India (CCI) and Foreign Investment Promotion Board (FIPB) were discussed in this context.

8. In the opinion of the Ministry of Health & Family Welfare, these concerns can be best and effectively addressed through the FIPB route. CCI is an independent statutory body and can consider cases of takeovers/acquisitions as per the legal mandate given to them. The Ministry strongly feels that scrutiny by CCI of takeovers/acquisitions with a view to address the issues as in para 5 is neither workable nor practical. It is also not possible for

the Ministry of Health & Family Welfare (representing consumers and end users of medicines) to appear in legal proceedings before the CCI.

9. In this background, Ministry of Health & Family Welfare is firmly of the view that while CCI can discharge its mandated legal role in the context of takeovers/acquisitions, public health related concerns indicated above can and should be addressed on an immediate basis (without waiting for further takeovers/acquisitions) through the FIPB route. Hence, our proposal is to stipulate as part of FDI policy that FDI proposals into brown field projects with 51% or more equity to be acquired by pharma MNCs should be brought before the FIPB. Such cases may be considered by FIPB and a view taken on building in adequate safeguards to protect public health needs as mentioned above. This is not expected to affect the FDI flow into pharma sector as FDI will continue to be at 100% and green field projects would continue under the automatic route. This marginal procedural correction in FDI policy should not be construed as a negative signal.

10. In this connection, it is also relevant to note that the High Level Expert Group on Universal Health Coverage set up by the Planning Commission in its Report recently submitted to the Government has also made a recommendation that we need to urgently revisit India's FDI regulations to amend the present rules on an automatic route of 100% of foreign players in the Indian industry to less than 49% so as to retain pre-dominance of Indian Pharmaceutical Companies and preserve our self-sufficiency in drug production.

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