Economics Conference 2007

Presidency College

Paper on

Economic hazards caused due to an Imperfect Market Structure and Asymmetric Information in the Pharmaceuticals Market

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ABSRACT

Following the TRIPS Agreement, rising satisfaction amongst the global pharmaceutical giants is coupled with an increasing discontent and concern about the poor people all over the planet – industrialized countries not being any exceptions. The need of the hour is to find out a compromise theory acceptable to both the warring factions. As the monopolistic market, resulting from TRIPS Agreement, has given absolute power to the pharmaceutical giants, they, being no exception to the dictum that absolute power corrupts absolutely, need to be strictly kept under vigilance for the welfare of the society globally. This paper deals with the avenues and methods of corruption adopted by the said firms and some innovative suggestions of dealing with those problems maximizing social welfare.

Key words: **Monopoly, Asymmetric information, Adverse selection, Moral hazard, Pharmaceutical giants, Brand drugs, Generic drugs, Medical Representatives, DTCA.**

SOME PHARMACEUTICAL TERMINOLOGIES USED

Brand drug:	**Drugs marketed under patent protection by the patent holder company.**
Generic drug:	**True copy of a brand drug, having similar efficacy.**
Reverse engineering:	**Alternative method of manufacture other than original manufacturing method used by original inventor / innovator of the drug.**
Therapeutic efficacy:	**Effectiveness in treatment.**
Clinical trial:	**Use of newly developed chemical formulation on human being to test it efficacy and adverse effects**
Essential drugs:	**Drugs, which are needed minimally for treating the all types of diseases. W.H.O. publishes a list of essential drugs every year.**
Unethical drugs:	**Drug formulations, which are not recommended in pharmacopoeia.**
Spurious drugs:	**Drugs having no therapeutic effect, and may contain harmful chemicals.**
“Novel” drugs:	**Drugs whose formulations are not recommended in any pharmacopoeia, but created at random at the will of the companies.**

Life is invaluable. Thus drugs those help to save life are priceless, although, they do come with a price tag. But when the large and powerful pharmaceutical companies meddle with the manufacturing and distribution process of the drugs, then they are indirectly attempting to set a price on human lives. Also, when these companies tamper with the price and quality of drugs, just to earn some extra profits, then, they are in a way denying people the most fundamental right – the right to life.

There are two major ways in which economic hazards are inflicted on people :

1. **IMPERFECT MARKET STRUCTURE : The handful of pharmaceutical giants, join hands and practically form a monopoly, and set a very high price, almost regardless of the purchasing power of the people.**

2. **ASYMMETRIC INFORMATION : Those pharmaceutical giants very often spread incomplete and / or incorrect information through various unethical ways. This causes wrong selection of drugs and health hazards – both of which lead to increasing economic problems for people.**

Let us discuss the burning issue of the day under two separate sections:

SECTION I : **Economic hazards caused by an essentially monopolistic market; and**

SECTION II : **Economic hazards due to asymmetric information.**

SECTION - I

IMPREFECT MARKET STRUCTURE :

A. HISTORY OF INDIAN PHARMACEUTICAL POLICIES AND INDUSTRIES:

Modern Indian pharmaceutical history dates back to the Bengal Chemicals and Pharmaceuticals Works in pre-independent India – in 1901. But, the pharmaceutical industry in pre-independent India did not progress much, causing dependence on imported drugs.

After independence, the first comprehensive drug policy came up in the year *1975* under the name of Foreign Equity Regulations Act. The policy had some important feature, viz, encouraging R & D, abolishing brand name drugs, *licensing only 117 drugs* which were considered sufficient for most of the diseases in India, maintaining quality of drugs, spreading unbiased information about drugs and monitoring drug reactions.

Next policy came up in *1978*, followed closely by *Drug Prices Control Order in 1979*, which put 347 drugs under price control classifying the drugs according to their importance, such as :

Life saving drugs	**:**	**40% profit**
Essential drugs	**:**	**55% profit**
Non-essential drugs	**:**	**75% profit**
Other drugs	**:**	**No control**

But, this policy did not have any provision to force firms to produce the life saving and essential drugs. The firms, therefore, misused the liberty to choose to manufacture those drugs, which were more profitable.

Next came the Drug (Prices Control) Order of 1987, wherein the number of drugs under price control were reduced from 347 to 142 and profit margins were raised.

The drug policy of *2002*, relaxed price control even more, and kept less than 40 drugs under price control. This has led to a boom in pharmaceutical industry in India, leading to uncontrolled manufacture of drugs – mostly non-essential and unethical, accumulating a staggering number of drugs in Indian market – about 3 lac preparations.

B. THE PATENT LAWS :

The first patent act in India dates back to *1856*, the next one being the *Patents and Design Act of 1911*. The latter one allowed patents to drugs, enabling, expectedly, the MNCs to take complete control of the market and charge extravagant prices. Prices of drugs in India, at that time, was ranked as the highest in the world.

In the post-independent era, the Indian Patents Act of 1970 excluded drugs altogether. One of its very important features was the Automatic Right to License, which safeguarded life saving drugs especially. The resultant boom in Indian pharmaceutical industry produced large volumes of high quality generic drugs, using reverse engineering, at much lower price, recording a turnover of over *$1.5 billion* in 2001.

It was but obvious that the global pharmaceutical giants based mainly in *USA, Japan and Germany*, opposed this boom vehemently. They pressurised, through the Governments of industrialised countries to impose patent restriction through World Trade Organisation. Finally, in the year 1994, they became successful to include India under the umbrella of patent act. India signed *Trade Related Intellectual Property Rights (TRIPS)* Agreement, which imposed a few vital (and potentially dangerous for developing and underdeveloped countries, and even, for the poor section of industrialised countries) provisions :

1. **Provision for granting of patents for pharmaceutical products and processes,**

2. **The patent holders, who will reserve exclusive manufacturing marketing right, will hold the patents for 20 years,**

3. **Patent will be granted irrespective of whether the applicant itself produced the drug or procured the drug from other source, say imported it from another country or bought it from some other research laboratory, and**

4. **In case the holder of the patent lodges a legal complaint against some firm for producing similar or generic drugs, then the onus of proving itself 'not-guilty' lies with the defendant.**

Under relentless pressure from the community of some industrialised countries for adoption of the provisions of TRIPS, Government of India, finally, introduced the Patents (Amendments) Act in *2005*, where the drugs were again included and moreover, processes for all drug productions were also included. This allowed a potential monopoly of a handful of MNC pharmaceutical giants in India, causing rising price of drugs, and thereby, of treatment cost.

Rising discontent in, specially, Least Developed Countries, led to the Doha meet in 2001, which culminated in releasing *Doha 'Declaration* on the TRIPS Agreement and Public Health'. This Declaration allowed to countries to use the exceptions of TRIPS for public health : *Compulsory Licensing* and *Parallel Imports.*

Under Compulsory Licensing, a government can allow manufacture of generic drugs, paying a reasonable royalty to the patent holding company. Provision of Parallel Import allows a government to shop in international market for the cheapest generic version of the patented drug marketed in its country. These provisions brought fresh air in the pharmaceutical market in India.

C. DRUG PRICE IN ESSENTIALLY MONOPOLISTIC MARKET :

Taking shelter, expectedly, behind the TRIPS Agreement, the few pharmaceutical giants – mainly from three industrialised countries – USA, Japan and Germany, gained control over overwhelmingly major share of global pharmaceutical market.

YEAR	SHARE IN GLOBAL PHARMACEUTICAL MARKET	
	LEADING 10 FIRMS	LEADING 20 FIRMS
1998	35.9%	57.2%
2000	About half	About two thirds

One important chain of events occurred since the advent of TRIPS Agreement – the mega mergers of pharmaceutical giants. Some examples : Glaxo Wellcome with SmithKline Beecham, Pfizer and Warnes Lambert, Hoechst-Merion with Merrell and Rhone-Poulenc forming Aventis, etc.

Apart from mega merger, an unholy cartel amongst the pharmaceutical giants have resulted in an essentially monopolistic market.

D. EFFECTS ON PRICE OF DRUGS AND TREATMENT COST:

a) **The companies get the freedom to charge fabulous and irrational profit – as high as *300 to 500%,* and they get away with it as the demand is very inelastic;**

b) **The companies throttle down the generic market by misusing the intellectual property rights, abolishing competition from generic drugs within the period of *20 years'* protection for their patents;**

c) To stop the generic manufacture of counterparts of popular mother drugs, even after expiry of patent protection after 20 years, the companies unscrupulously resort to ***'ever-greening'***, that is, they take fresh patent, before expiry of the patent protection, of similar compounds, by minor alteration of the chemical composition of the mother drugs.

d) ***First Degree Price Discrimination*** is another effect of this type of drug market. The companies market the drugs at various prices, in different countries, fully exploiting the reservation prices of consumers in those countries.

E. SOME RELEVANT STATISTICS :

Let us discuss the effects on drug prices with the help of some statistical data herein below.

Comparative prices of some Branded Drugs (i.e., drugs marketed by companies holding patent) and Generic Drugs :

BRANDED DRUG	GENERIC DRUG	PRICE PER TABLET (IN US$)	
		BRANDED DRUG	GENERIC DRUG
Allegra	Fexofenad	0.78	0.57
Vasotek	Enalapril	1.49	0.37
Xanex	Alprazolam	3.08	0.30
Pritosec	Omeprazol	3.83	0.91

Comparison of prices of some of the generic drugs in USA / Canada and India :

DRUG	PRICE PER TABLET (IN US$)	
	USA / CANADA	INDIA
Stavudine 30 mg	2.25	0.43
Nevirapine	3.58	1.32
Lamivudine	4.33	0.80

Statistics on manufacturer prices of 193 most widely used branded drugs :

YEAR	INCREASE IN MANUFACTURER'S PRICE	INFLATION RATE (%)
2000	4.1	3.4
2001	4.7	2.8
2002	6.1	1.6

2003	7.0	2.3
2004	7.1	2.7
2005	6.0	3.4
2006	6.2	3.2

Cumulative percentage change in manufacturer price between 2000 and 2006 = 38% to 129% of 2000 price.

Cumulative increase of cost of treatment from 2000 to 2006 using these drugs is highest upto US$ 822.

Distribution of percentage change of 193 widely used branded drugs in 2006 - rate of inflation in 12 months being 3.2%:

NO OF DRUGS	PERCENTAGE INCREASE
6	No change
4	0.1 – 2.5%
64	2.6 – 5.0%
75	5.1 – 7.5%
27	7.6 – 10.0%
12	10.1 – 15.0%
5	15.1 – 29.8%

F. MATHEMATICAL MODEL :

Let us now build a mathematical model to illustrate the ill-effects of an essentially monopolistic market, and, also to try and derive the remedy to the imperfection in the market structure.

Let there be 2 cases :

CASE 1 :

Present situation where the pharmaceutical giants join hands to form a cartel and create a monopolistic market.

CASE 2 :

Future situation where the market has become perfectly competitive and the pharmaceutical giants have to compete with the generic drug companies.

The price of a drug is determined after the completion of four major stages of production. They are :

1. **Research & development and clinical trials**
2. **Patenting**
3. **Manufacturing**
4. **Registration**

Assumption :

a) **Cost incurred for patenting and registration is negligible.**
b) **Total fixed cost (TFC) is the same for producers of both the markets**

CASE 1

MONOPOLISTIC MARKET

Let the cost incurred for R&D be $P_{RD}Q_M$

Let the cost incurred for manufacturing be $P_{MA}Q_M$

Therefore, total variable cost is :

$$TVC = P_{RD}Q_M + P_{MA}Q_M + ßQ_M^2$$

where, ß = rate of change of marginal cost, ß > 0.

Total cost is :

$$TC = P_{RD}Q_M + P_{MA}Q_M + ßQ_M^2 + TFC, \quad TFC > 0$$

Total revenue is :

$$TR = P_MQ_M$$

Let us assume that the demand function is a linear one.

Therefore, demand function is :

$$P_M = a - bQ_M, \quad a, b > 0$$

Substituting the value of P_M in TR, we get :

$$TR = (a - bQ_M) Q_M$$

The first-order condition of profit maximisation of a monopolist is :

$$MR = MC$$

Thus, maximising profit we get,

$$a - 2bQ_M = P_{RD} + P_{MA} + 2ßQ_M$$

$$\Rightarrow Q_M^* = \frac{a - P_{RD} - P_{MA}}{2ß + 2b}$$

This is the equilibrium quantity.

The second-order condition for profit maximisation is :

Slope of MR < slope of MC
Slope of MR = -2b
Slope of MC = 2ß

Therefore, profit is maximised.

Substituting the value of Q_M^* into the demand function we get :

$$P_M^* = a - bQ_M^*$$

$$= a - b \left\{ \frac{a - P_{RD} - P_{MA}}{2ß + 2b} \right\}$$

$$= \frac{2aß + 2ab - ab + bP_{RD} + bP_{MA}}{2ß + 2b}$$

$$\Rightarrow P_M^* = \frac{2aß + ab + bP_{RD} + bP_{MA}}{2ß + 2b}$$

This is the equilibrium price.

CASE 2

PERFECTLY COMPETITIVE MARKET

Let the cost incurred for R&D be $P_{RD}Q_C$

Let the cost incurred for manufacturing be $P_{MA}Q_C$

Therefore, total variable cost is :

$$TVC = P_{RD}Q_C + P_{MA}Q_C + ßQ_C^2$$

where, ß = rate of change of marginal cost, ß >0.

Total cost is :

$$TC = P_{RD}Q_c + P_{MA}Q_c + ßQ_c^2 + TFC, \quad TFC > 0$$

Total revenue is :

$$TR = P_cQ_c$$

Therefore, profit is :

$$Π = TR - TC$$

$$= P_cQ_c - P_{RD}Q_c - P_{MA}Q_c - ßQ_c^2 - TFC$$

The first-order condition of profit maximisation is :

$$\frac{δΠ}{δQ_C} = 0$$

$$\Rightarrow P_C - P_{RD} - P_{MA} - 2ßQ_C = 0$$

$$\Rightarrow Q_C = \frac{P_C - P_{RD} - P_{MA}}{2ß}$$

The second-order condition for profit maximisation is :

$$\frac{\delta^2 \Pi}{\delta Q_C^2} < 0$$

Here, $\frac{\delta^2 \Pi}{\delta Q_C^2} = -2ß$

Therefore, profit is maximised.

There are 'n' number of firms in the industry.

Therefore,

$$Q_C^1 = nQ_C$$

$$= n \left\{ \frac{P_C - P_{RD} - P_{MA}}{2ß} \right\}$$

Let us assume that the demand function facing the industry is a linear one.

Therefore, the demand function is :

$$P_C = a - bQ_C^1, \quad a, b > 0$$

$$\Rightarrow Q_C^1 = \frac{a - P_C}{b}$$

The supply curve facing the consumers is :

$$Q_C^1 = n \left\{ \frac{P_C - P_{RD} - P_{MA}}{2ß} \right\}$$

At equilibrium,

Demand = Supply

$$\Rightarrow \frac{a - P_C}{b} = \frac{nP_C - nP_{RD} - nP_{MA}}{2ß}$$

$$\Rightarrow P_C^* = \frac{2aß + bnP_{RD} + bnP_{MA}}{2ß + bn}$$

This is the equilibrium price.

Substituting the value of P_C^* into the demand function we get :

$$Q_C^{1*} = \frac{a - P_C^*}{b}$$

$$= \frac{abn + 2aß - 2aß - bnP_{RD} - bnP_{MA}}{2ßb + b^2 n}$$

$$\Rightarrow Q_C^{1*} = \frac{an - nP_{RD} - nP_{MA}}{2ß + bn}$$

This is the equilibrium quantity.

OBSERVATIONS MADE FROM THE MODEL

OBSERVATION 1 :

Price charged by the monopolist is higher than the price charged in the competitive market.

$$P_M^* - P_C^* = \frac{2a\beta + ab + bP_{RD} + bP_{MA}}{2\beta + 2b} - \frac{2a\beta + bnP_{RD} + bnP_{MA}}{2\beta + bn}$$

$$= \frac{2abn\beta + ab^2n - 2ab\beta - b^2nP_{RD} + 2b\beta P_{RD} - b^2nP_{MA} + 2b\beta P_{MA} - 2bn\beta P_{RD} - 2bn\beta P_{MA}}{(2\beta + 2b)(bn + 2\beta)}$$

$$= \frac{b(P_{RD} + P_{MA})(2\beta - bn - 2n\beta) + abn(2\beta + b) - 2ab\beta}{(2\beta + 2d)(bn + 2\beta)} > 0$$

This implies that, $P_M^* > P_C^*$

OBSERVATION 2 :

Quantity produced in a monopolistic market is less than the quantity produced in the competitive market.

In both the above cases, the demand curves we have considered are general downward sloping curves graphed in the price-quantity plane. That is, according to the above model, price and quantity are inversely related to each other. Therefore, as we have mathematically proved that $P_M^* > P_C^*$**, we can conclude that** $Q_M^{1*} < Q_C^{1*}$**.**

OBSERVATION 3 :

The profit earned by the monopolist is much more than the profit earned by firms under competition.

Total revenue earned by a monopolist is :

$$TR_M = P_M^* Q_M^*$$

$$= \frac{(2a\beta + ab + bP_{RD} + bP_{MA})(a - P_{RD} - P_{MA})}{(2\beta + 2b)^2}$$

$$= \frac{2a^2\beta - 2a\beta P_{RD} - 2a\beta P_{MA} + a^2b - bP_{RD}^2 - 2bP_{RD}P_{MA} - bP_{MA}^2}{(2\beta + 2b)^2}$$

Total cost incurred by a monopolist is :

$$TC_M = P_{RD}Q_M^* + P_{MA}Q_M^* + ßQ_M^{*2} + TFC$$

$$= \left[\frac{a - P_{RD} - P_{MA}}{2ß + 2b}\right]\left[P_{RD} + P_{MA} + \frac{aß - ßP_{RD} - ßP_{MA}}{2ß + 2d}\right] + TFC$$

Simplifying the above expression, we get :

$$TC_M = \frac{2abP_{RD} + 2abP_{MA} + a^2ß - ßP_{RD}^2 - 2ßP_{RD}P_{MA} - 2bP_{RD}^2 - 4bP_{RD}P_{MA} - ßP_{MA}^2 - 2bP_{MA}^2}{(2ß + 2b)^2} + TFC$$

Therefore, profit is :

$$\Pi_M = TR_M - TC_M$$

$$= \frac{a^2ß - 2aßP_{RD} - 2aßP_{MA} + a^2b + bP_{RD}^2 + bP_{MA}^2 + 2bP_{RD}P_{MA} - 2abP_{RD} - 2abP_{MA} + ßP_{RD}^2 + 2ßP_{RD}P_{MA} + ßP_{MA}^2}{(2ß + 2b)^2} - TFC$$

Total revenue earned by firms under perfect competition is :

$$TR_C = P_C^* \; Q_C^{1*}$$

$$= \frac{(2aß + bnP_{RD} + bnP_{MA})(an - nP_{RD} - nP_{MA})}{(bn + 2ß)^2}$$

$$= \frac{2an^2ß - 2anßP_{RD} - 2anßP_{MA} + abnP_{RD} + abnP_{MA} - bn^2P_{RD}^2 - bn^2P_{MA}^2 - 2bn^2P_{RD}P_{MA}}{(bn + 2ß)^2}$$

Total cost incurred by a firm under perfect competition is :

$$TC_C = P_{RD}Q_C^{1*} + P_{MA}Q_C^{1*} + ßQ_C^{*2} + TFC$$

$$= \left[\frac{an - nP_{RD} - nP_{MA}}{2ß + 2d}\right]\left[P_{RD} + P_{MA} + \frac{anß - ßP_{RD} - nßP_{MA}}{2ß + 2d}\right] + TFC$$

Simplifying the above expression, we get :

$$TC_C = \frac{abn^2P_{RD} + 2anßP_{RD} + abn^2P_{MA} + 2anßP_{MA} + a^2n^2ß - 2an^2ßP_{RD} - 2an^2ßP_{MA} - bn^2P_{RD}^2 - 2nßP_{RD}^2 - 2bn^2P_{RD}P_{MA} - 4nßP_{RD}P_{MA} + n^2ßP_{RD}^2 - bn^2P_{MA}^2 - 2nßP_{MA}^2 + 2n^2ßP_{RD}P_{MA} + n2ßP_{MA}^2}{(bn + 2ß)^2} + TFC$$

Therefore, Profit is :

$$\Pi_C = TR_C - TC_C$$

$$= \frac{2an^2ß - 4anßP_{RD} - 4anßP_{MA} + abnP_{RD} + abnP_{MA} + abn^2P_{RD} + abn^2P_{RD} + a^2n^2ß - 2an^2ßP_{RD} - 2an^2ßP_{MA} - 2nßP_{RD}^2 - 2nßP_{MA}^2 + n^2ßP_{MA}^2 + n^2ßP_{RD}^2 - 4nßP_{RD}P_{MA} + 2n^2ßP_{RD}P_{MA}}{(bn + 2ß)^2} - TFC$$

Therefore,

$$\Pi_M - \Pi_C = \frac{a^2ß - 2aßP_{RD} - 2aßP_{MA} + a^2b + bP_{RD}^2 + bP_{MA}^2 + 2bP_{RD}P_{MA} - 2abP_{RD} - 2abP_{MA} + ßP_{RD}^2 + 2ßP_{RD}P_{MA} + ßP_{MA}^2}{(2ß + 2b)^2} - TFC$$

$$- \frac{2an^2ß - 4anßP_{RD} - 4anßP_{MA} + abnP_{RD} + abnP_{MA} + abn^2P_{RD} + abn^2P_{MA} + a^2n^2ß - 2an^2ßP_{RD} - 2an^2ßP_{MA} - 2nßP_{RD}^2 - 2nßP_{MA}^2 + n^2ßP_{MA}^2 + n^2ßP_{RD}^2 - 4nßP_{RD}P_{MA} + 2n^2ßP_{RD}P_{MA}}{(bn + 2ß)^2} + TFC$$

$$= \frac{[(a^2ß - 2aßP_{RD} - 2aßP_{MA} + a^2b + bP_{RD}^2 + bP_{MA}^2 + 2bP_{RD}P_{MA} - 2abP_{RD} - 2abP_{MA} + ßP_{RD}^2 + 2ßP_{RD}P_{MA} + ßP_{MA}^2)(bn + 2ß)^2] - [(2an^2ß - 4anßP_{RD} - 4anßP_{MA} + abnP_{RD} + abnP_{MA} + abn^2P_{RD} + abn^2P_{MA} + a^2n^2ß - 2an^2ßP_{RD} - 2an^2ßP_{MA} - 2nßP_{RD}^2 - 2nßP_{MA}^2 + n^2ßP_{MA}^2 + n^2ßP_{RD}^2 - 4nßP_{RD}P_{MA} + 2n^2ßP_{RD}P_{MA})(2ß + 2b)^2]}{(2ß + 2b)^2 (bn + 2ß)^2} > 0$$

Hence, $\underline{\Pi_M > \Pi_C}$.

Thus, here we find that the price charged in a monopolistic market is more than that charged in a perfectly competitive market and, also, the quantity produced is less than that produced in the perfectly competitive format.

Therefore, the obvious solution to an imperfect market is the conversion of the market to a perfectly competitive one.

But, a competitive market is not as heavenly as it sounds. The biggest problem in a competitive market is asymmetric information. The large players use concealed or manipulated information and action to combat competition. And, asymmetric information is a much greater evil to society than a monopolistic market as will be discussed in the following section.

SECTION – II

ASYMMETRIC INFORMATION :

Today, the pharmaceuticals market in India is growing at the rate of *8-9%* per annum, and is currently worth about *US $4.5 billion.* But, India is essentially a producer of generic drugs. Thus, the pharmaceutical giants, which produce drugs under specific brand names, are facing stiff competition from the domestic market.

Therefore, to fight competition, the MNCs resort to unethical and illegal activities. These activities help them raise the price of drugs artificially or compromise on the quality of the drugs. That is, they either conceal essential information or conduct some unscrupulous activities which remain hidden from public eye, and, even, sometimes from expert eyes.

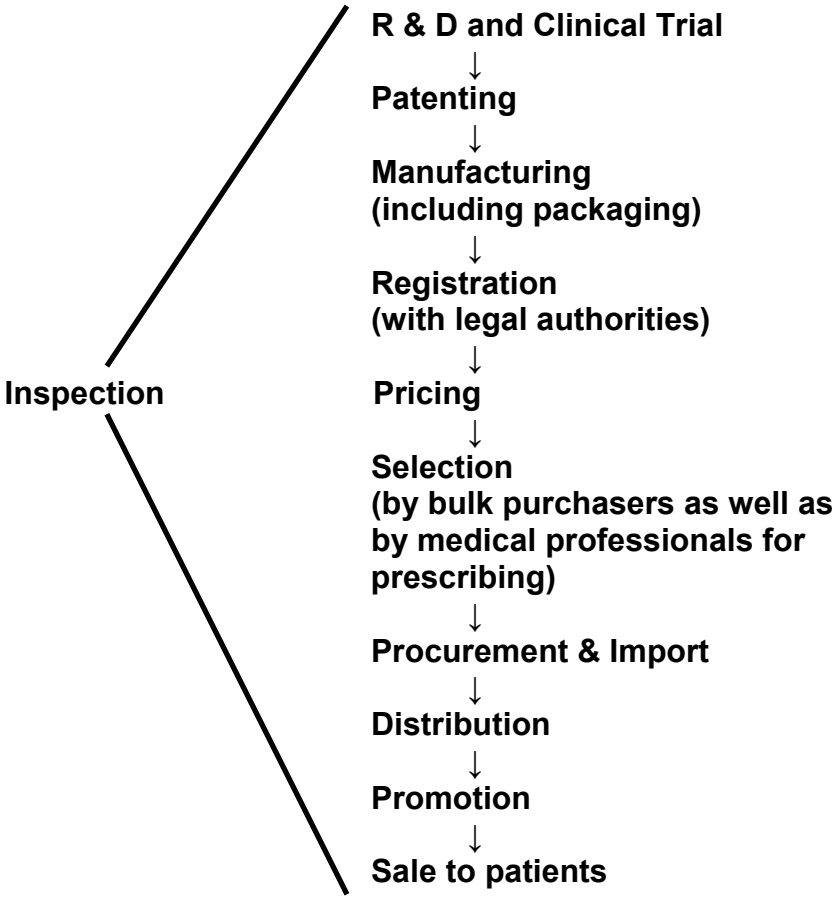
A. TYPES OF ASYMMETRIC INFORMATION :

i) **ADVERSE SELECTION** : **It is the phenomenon of *hiding information* from ultimate consumers and medical service providers.**

ii) **MORAL HAZARDS** : **It involves *hiding actions* from consumers and medical service providers.**

B. STAGES OF PHARMACEUTICAL PRODUCTION :

The stages can be schematically represented as follows :



ADVERSE SELECTION :

Information is hidden from the beneficiaries by the pharmaceutical firms throughout the chain described above. Let us discuss the stages one by one herein below.

1. R & D AND CLINICAL TRIALS : Adverse selection occurs in this stage in two ways :

a. **Participants of clinical trials are often given incorrect or incomplete information about the effects, side effects and adverse reactions of the drugs used on them. This helps the companies to get more participants at the cost of their safety.**

b. **R & D costs are often hyper-inflated. The firms generally claim that their R & D cost ranges between *US$ 350 to 500 million* per invention or innovation of new chemical substance. But independent studies has put this amount at *US$ 30 to 160 millions*. In fact, R & D takes up only about *10 to 20%* of total expenses, while marketing and administrative expenses account for about 30 to 40%. This is primarily the reason why firms include R & D expenditure into cost on fixed assets in**

their balance sheets. Expectedly, the effect of this hyper-inflation of costs is felt directly on prices.

2. PATENTING : Patenting authorities are often given the wrong information about the drugs – their positive effects are blown out of proportion, suppressing their side effects or adverse effects. Thus patents are sometimes granted to ineffective or potentially harmful drugs.

3. SELECTION / PROCUREMENT & IMPORT / DISTRIBUTION / PROMOTION / SALE : The firms more often than not spread incorrect information about their drugs to concerned authorities / medical professionals / pharmacists for gaining undue benefit in each and every of the aforesaid stages. This results into wrong selection / distribution / recommendation / sale of drugs. Thus unethical and non-essential drugs are rampantly sold, creating health hazards. Furthermore, costlier drugs are sold in spite of availability of cheaper alternatives of similar efficacy and potency, causing financial loss.

Let us consider a shocking example of adverse selection in recent past. A pharmaceutical giant like Merck & Co. Inc. launched a drug under the brand name of *VIOXX*. Claiming to be highly efficacious pain killer, the company suppressed its dangerous effect on patients' hearts. The medicine was patented and passed the stages of drug testing, and was finally marketed. Fortunately, the medicine had to be withdrawn due to strong protests from various sectors including the World Health Organisation. According to WHO statistics, *some 88 to 140 thousands of people had heart attacks, of which 40% were fatal* out of estimated 80 million users using the drug.

Another extreme example of adverse selection has been unveiled by the US FDA. According to its survey, *84% of drugs produced by US firms have little or no therapeutic value*, but are being profusely prescribed globally. All they successfully do is put unnecessary economic burden on the society as a whole.

One of the most shocking news about Indian pharmaceutical market came recently from none other than WHO, who commented that about *35% of 3 lacs of medicinal products available in Indian market are 'nothing better than talcum powder' and about a fifth of that 'contains harmful chemicals'*. It goes beyond saying that these huge number of unethical / non-essential drug formulations are causing immense economic burden on the entire Indian society.

The most important weapons for spreading incorrect information to various sectors are :

a. Medical representatives
b. Reading materials supplied by the companies to medical professionals
c. Company-sponsored continuing medical education programs
d. Direct to consumer advertisements.

MORAL HAZARDS :

Carefully concealed unethical and illegal activities are carried out by the pharmaceutical firms throughout the chain described above, causing not only direct financial burden on the patients, but also paralysing the national economy by high risk of mortality and morbidity. Let us discuss the stages one by one herein below.

1. **R & D AND CLINICAL TRIALS** : Firms conduct more research work on issues that are beneficial for earning more profits, rather than on generating drugs of social importance. More research is done to formulate new non-essential drugs, which generally do not have strict price controls, neglecting research on new life-saving and essential drugs, having stricter price controls.

2. **PATENTING AND REGISTRATION** : During the processes of patenting and legal registration, the pharmaceutical companies inflict moral hazards in two ways :

a. They claim these new formulations as their own R & D products, concealing often that those had been bought from some other source, viz., university or other educational institutions. This causes unnecessary addition of R & D cost on the price of new drugs.

b. Even with adverse selection in relation to divulging the truth relating to their new formulations, as described above, patenting and legal registration often needs further unscrupulous activities. Bribery is a strong means by which the concerned officials are influenced to grant patent as well as legal registration. The society is, in this way, cheated, causing, once again, direct as well as indirect economic losses. Prices of drugs rocket up due to addition of all these unwarranted hidden costs.

Studies suggest that US firms have spent over US$ 1 billion on lobbying politicians and powerful groups in the USA over the last 10 years. In fact, 10 – 25% of procurement spending is lost to corruption every year. Be it noted here that these are, in all probability, much understatements, as the true picture, which is strictly confidential, may be even worse.

3. **MANUFACTURE (INCLUDING PACKAGING)** : This sector is an important component constituting large burden on the country's

economy. The most important issue is unnecessary manufacture of unwanted formulations, which includes :

a. **Unethical and non-essential drugs,**
b. **Spurious drugs and "novel" drugs,**
c. **Counterfeited drugs.**

It is a matter of concern for all Indians that Indian market is flooded with such drugs. Some terrifying examples are given herein under :

a. Unethical and non-essential drugs :

CATEGORY OF DRUG	ESSENTIAL DRUGS	UNETHICAL / NON-ESSENTIAL COUNTERPARTS	TRADE NAMES
Anti-amoebic / anti-giardial agents	# Diloxamide # Metronidazole	Tinidazole	# Tini # Tiniba
Antacid / anti-ulcer agents	# Aluminium hydroxide # Magnesium hydroxide # Ranitidine	# Famotidine # Omeprazole # Pantoprezol # Lansoprazole # Rabeprazole # Simethicone # Dimethicone # Magnesium trisilicate # Sodium carboxymethyl cellulose	# Famocid # Omez # Pantodac # Lan Majority of antacid prepns.
CATEGORY OF DRUG	**ESSENTIAL DRUGS**	**UNETHICAL / NON-ESSENTIAL COUNTERPARTS**	**TRADE NAMES**
Oral rehydration formula	Glucose 13.5 g/l Sodium chloride 2.6 g/l Potassium chloride 1.5 g/l Trisodium citrate dihydrate 2.9 g/l	Preparations in violation of the suggested composition	# Electral # Electrobion
Antibiotic eye prepns.	# Gentamicin # Tetracycline	Host of antibiotic ophthalmic preparations	# Renicol # Ciplox # Chlor-mycetin

			# Cifran # Neosporin # Norflox
Anti-pyretic – Analgesic	# Acetyl salicylic acid # Ibuprofen # Paracetamol	# Analgin # Destropropo-xyphene # Acetamino-phen # Propoxyphene	# Novalgin # Parvon # Proxytab # Proxyvon

b. Spurious / "novel" drugs :

COMPOSITION	TRADE NAMES
Paracetamol + Ibuprofen	# Ibugesic Plus # Ibucon Plus # Ibuclin
COMPOSITION	**TRADE NAMES**
Norfloxacin + Metronidazole	# Normet # Normetrogyl
Addition of Simethicone / Disimethocone Oxythazaine in Antacids	# Digene # Polycrol Forte Gel # Mucaine
Ciprofloxacin / Ofloxacin + Tinidazole	# Ciplox TZ # Floxur TZ # Oflomac TZ
Drugs marketed under the label of 'Ayurvedic Medicines' – many are self made combinations – no strigent quality control	Several drugs marketed, e.g., # Bonnisan, # Liv 52, # Spemen Forte etc.
Cough mixtures	Innumerable "novel" combinations of various mother drugs – expectorant, anti-tussive, antihistaminics, decongestants, etc. are marketed at will under the group name of 'cough formulae'
Carminatives and digestive enzymes	Innumerable self-made "novel" combinations of digestive enzymes, vitamins, antiflatulents, antacids and so-called carminatives are marketed rampantly.

Another shocking phenomenon has been rampantly occurring in Indian pharmaceutical market : medicinal preparations are altered without changing their brand name. This may occur in two ways :

a. One or more components in one particular brand of drug is silently changed to gain more profit, most often without

information to medical professionals, leaving aside the question of common people.

b. Another method is changing of the composition altogether without changing the popular brand names.

Examples :

TRADE NAME	PREVIOUS COMPOSITION	PRESENT COMPOSITION	REMARKS
Cetrizet-D	Cetrizine + pseudoephe-drine	Cetrizine + phenyl-ephrine	Pseudoephedrine, having price control under Govt. of India, was included – costing Rs. 8.11 per 10 tabs. When the drug earned reputation, pseudoephedrine was silently replaced by phenylephrine, having no price control – hiking price of Rs.28.20 per 10 tabs., earning 350% profit.
Movon	Piroxicam	Aceclofenac	The composition is changed to earn more profit
Incidal	Mebhydolin	Cetrizine	The composition is changed to replace obsolete drug.

The point to be noted is that, in these actions of pharmaceutical companies not only hike prices of drugs by many folds, but also cause serious health hazards, adding to loss in personal, social as well as national economy. The indications, uses, dosage schedules, side effects, adverse effects, contra-indications, specific indications – everything change from the old preparation to the newer one, without proper intimation and wide publicity of such changes.

4. SELECTION / PROCUREMENT & IMPORT / DISTRIBUTION / INSPECTION:

All these steps are heavily manipulated by several methods. Some of which are :

a. Bribery,
b. Donations,
c. Unethical commissions,
d. Other unethical offers,

e. **Gifts,**
f. **Free samples.**

All these are utilised to influence selection of drugs for bulk purchases at various levels, for bulk import, for prescribing medicines to patients by medical professionals, for bulk procurement and distribution by distributors and pharmacists, and for *preferential over-the-counter (OTC)* sale of drugs by pharmacists.

It is an unfortunate situation in India that the medicinal drugs, which are obsolete or banned in other countries, *dumped in India* for sale of the remaining stock and for realisation of extra profit for the establishment of such manufacture. A few such latest examples are :

DRUGS BANNED ELSEWHERE	AVAILABLE IN INDIA
Nimesulide	# Nise # Nimulid
Analgin	# Novalgin
Furazolidone	# Furoxone # Kaltin MF

Selection of drugs is also influenced by unscrupulous use of similar names for different formulations. Exploiting popular brand names, medicines of different composition are marketed with similar sounding names.

Examples :

DRUG 1		DRUG 2	
BRAND NAME	COMPOSITION	BRAND NAME	COMPOSITION
Sivoxol	Salbutamol, theophylline, ambroxol – used for asthma	Sivozol	Ofloxacin, tinidazole – antidiarrhoeal
Tocan	Clindamycin - antibacterial	Tocon	Ketokonazol - antifungal
Alzol	Albendazol – deworming agent	Alzot	Alprazolm - anxiolytic

These give the companies undue advantage in marketing, but causes health hazards by use of improper medicine.

5. PROMOTION AND SALES : This is one of burning issues of the day in relation to pharmaceutical industries globally. This is the stage, where maximum damage is done to the society and its economy. Promotion may be defined as "all informational and persuasive activities my manufacturers and distributors, the effect of which is to induce the

prescription, supply, purchase and / or use of medicinal drugs" (World Health Organisation).

This broad base is misused to the maximum by the pharmaceutical companies for their unlawful gains. The major avenues through which, these unethical activities of the companies are performed, may be classified as follows :

a. **Medical representatives : some details are discussed herein below**
b. **Journal advertising : highlighting the products**
c. **Direct to consumer advertising (DTCA) : discussed herein under**
d. **Funding of physicians' 'opinion leaders' : discussed above**
e. **Sponsoring C.M.E. : for obliging a group of doctors and for spreading incorrect or incomplete information about their products**
f. **Distribution of reading materials : similar approach as above**
g. **Sponsorship of patient groups, professional societies: to promote unethically certain products for unlawful gains**
h. **Offer of increased commissions and special offers to the distributors and pharmacists : these help the products of a company to be selected, procured and sold over the counter as well as replacing originally prescribed drugs of doctors' prescriptions by persuading patients / parties.**

MEDICAL REPRESENTATIVES :

Perhaps one of the most talked about topic in pharmaceutical market is the rationale of appointing representatives by the companies. Honestly, representatives serve no good purpose in the medical world, but they act as Messiahs for the pharmaceutical companies. They are the bridge between sale of drugs on one hand and the pharmaceutical companies on the other. Extraordinarily high targets of sales are set for the representatives and are supported by all amenities and help – lawful and unlawful, from the companies to achieve them.

These representatives make good rapport with medical professionals, influencing them to write irrational prescriptions. The irrationality in medical prescriptions may be of various forms :

i) **Writing of unethical / non-essential drugs – examples of some such drugs have already been given herein above;**

ii) **Writing of useless / spurious drugs, having little or no therapeutic value – some relevant statistics have already been cited, revealing as high as more than one lac of medical drug preparation in Indian market are available, which are 'nothing better than talcum powder';**

iii) **Prescription of banned drugs, which are still available in the market – examples of drugs banned in other countries, but available in India, have been furnished above. There is another situation, when some drugs are banned in India and those drugs are sold for quite some time thereafter suppressing the said information, till the old stocks are exhausted;**

iv) **Prescription of costly drugs, when cheaper alternatives are available in the market. Some examples are :**

GROUP OF DRUGS	CHEAPER VERSION (DAILY TREATMENT COST IN INR) BASIC COST		COSTLY ALTERNATIVES (DAILY TREATMENT COST IN INR) BASIC COST	
	DRUG	COST	DRUG	COST
Antacid + Anti-ulcer	# Histac 150 mg # Zinetac 150 mg	1.00 1.05	# Ocid 20 mg # Lanzol 15 mg # Rabeloc 20 mg	5.46 2.42 5.95
Hepatitis B vaccine (single pediatric dose)	# Enevac # Bevac	85.00 55.00	# Engerix B	181.00
GROUP OF DRUGS	CHEAPER VERSION (DAILY TREATMENT COST IN INR) BASIC COST		COSTLY ALTERNATIVES (DAILY TREATMENT COST IN INR) BASIC COST	
	DRUG	COST	DRUG	COST
Deworm-ing agent	# Millibend # Emanthal	6.00 7.50	# Zentel # Combantrin A	16.00 14.83
Antihista-minics	CTZ	1.60	# Cetrizet # Alerid	3.00 3.15
Antibiotic (Ciprofl-oxacin)	Zoxane 500 mg	7.80	# Cifran 500 mg # Ciplox 500 mg # Ciprobid 500 mg	18.00 17.40 13.76
Antibio-tic (Ofloxa-cin)	Floxur 200 mg	9.60	Tarivid 200 mg	62.00
Thyro-xine	Roxin 100 mcg	0.18 per tab	Eltroxin 100 mcg	0.74 per tab

A stunning statistics reveals that in South Asia, one child is dying every second minute and writing of second line antibiotic (often unnecessarily) in place of first line of the

same group increases treatment cost by US$ 120 million per year at bulk purchase cost.

Surprises are not yet finished. Writing of antibiotics unnecessarily, adds US$ 100 to US$ 200 per annum in USA. In fact, global revenue for antibiotics is projected in the range of US$ 31 billions in 2009 and in India, *antibiotic sales constitutes 15.7% of total drug sales* – constituting the largest therapeutic group.

v) **Advice drugs unnecessarily without any additional therapeutic benefit – the worst offenders being antibiotics, which increase cost of treatment several folds, but more often than not without any additional benefit and are not indicated. Supportive drugs, like vitamin preparations, digestive enzymes, carminatives, appetite stimulating drugs, etc., adding to treatment cost unnecessarily.**

Such serious situation for the society is created by the representatives using several unlawful means, each and every item adding to the price of medicines and cost of treatment :

a. **Offer gifts ranging from a pen to a car. An interesting example, though of a neighbouring country, is the offer of a car for every 200 prescriptions of a high-priced drug. There is no reason to laugh at Pakistan for such a situation, because similar offers are rampantly made to Indian medical professionals also. Offer of air conditioner, refrigerator, television are often encountered in our country.**

b. **Sponsorship of personal benefits, like travel to conferences, specially, the overseas ones, entertainment programs at home, etc. is a part of such illegal transactions. These benefit the medical professionals not only by saving on their pockets, but also adding a feather in their hats by a propaganda to their patients that their doctors were out of station to attend 'international conferences' – sometimes, even, a publicity is made that the said doctors were 'invited as guest speakers'.**

c. **Sponsorship of continuing medical education (CME) programs, where good lunch (with beverages) and entertainments are offered to medical professionals. Be it noted here that the CMEs are organised on topics suitable for promotion of items launched by the sponsoring companies, presenting, often, distorted facts about their products.**

d. **Sponsoring medical professionals as speakers in various CME programs, allowing the said professional to make self-propaganda amongst the local doctor community, helping him to gain in his private practice.**

e. **Sponsorship of medical events keep interested groups of medical professionals obliged and the companies reap benefit by influencing those doctors, later on, to write irrational prescriptions as above.**
Some examples of extent of such sponsorship :

ORGANISATION	ITEM	AMOUNT (INR) DEMANDED IN 2006
National Conference on Pulmonary Diseases	Toilets	1 lac each
Indian Society of Critical Care Medicine	Principal sponsor	15 lacs
	Each lunch	5 lacs
	Banquet	10 lacs
Indian Orthopaedic Association	Sponsorship of "main hall"	10 lacs
	Each lunch	8 lacs
Indian Association of Surgical Oncology	Principal sponsor	4 lacs

In the year 2000, various companies organised 3 lacs of medical events for doctors in USA.

f. **Offer free samples of medicinal drugs to medical professionals, allowing them to use for personal requirement and, even, to sale in some instances. It has been shown in various studies that the purpose under which these samples are supplied to the medical professionals, often fail. But, in the process, the cost of drugs increase sky-high due to addition of all such costs.**

Representatives are also used to influence pharmacists to assist increased OTC sales. Those representatives are hailed as extremely useful ones who can make rapport with pharmacists in such a way that the products of their companies are only stocked in various pharmacies, rejecting the competitor companies'. Apart from OTC sale, doctors' prescriptions are tampered by supplying alternatives of the drugs originally prescribed by the doctors.

These representatives are also used to build rapport with executives for manipulating them for various unscrupulous gains of the companies.

Though this profession generates some employment, but the cost of maintenance of these representatives is substantial. That cost is added to price of drugs. An estimated *US$ 65.2 million* is spent for salary and other fringe benefits of medical representatives per year. Loss of welfare to the society due to these medical representatives out-weighs the benefit, if any, derived from them.

Therefore, the representatives of the pharmaceutical companies, popularly known as medical representatives, do more harm than good to the society. Innumerable voices have rightly been raised in favour of abolishing this profession.

A study reveals that some *3.4 million* visits have been estimated to have been paid by the medical representatives in Canada in the year 2000, distributing estimated 21.5 millions of free drug samples to the doctors.

DIRECT TO COMSUMER ADVERTISEMENT :

Advertisement of medicinal products, directly to the consumers, is not preferred by most of the doctors – studies reveal. But, pharmaceutical companies resort to the practice heavily, misleading consumers to buy – often wasting large sum of money, for purchasing medicinal drugs, many a times unnecessarily. Ignorant about their clinical indications, effects, dosage schedules, side effects, adverse effects and contra-indications, consumers expose themselves to the risk of potential health hazards. Economic losses occur due to buying products having no significant therapeutic effect, if at all. Health hazards cause loss in national economy too.

Powerful popular media are utilised by the companies for such purpose – mostly news papers, popular magazines, television advertisements etc. TV ads are the most powerful and popular audiovisual medium for the companies and they spend huge sum of money for such costly medium. All these sums are added to the prices of medicines.

An estimated *US$ 1.8 billions* is spent every year in recent times by the companies globally for DTCA.

One statistics :

In the year 2002, in USA alone, companies spent US$ 21 billions for promotion, comprising of 90% expenditure for promotion to doctors and about 10% for DTCA.

Let us now try to establish mathematically the direct effects of asymmetric information on the total cost incurred by the firms, which, in turn, will automatically have a direct bearing on the price that the firms charge.

C. MODEL ON ASYMMETRIC INFORMATION

Let there be two cases :

CASE 1 :

Situation where the market is truly perfectly competitive, i.e., consumers are fully informed about the activities of the firms and there is no asymmetric information in the market.

CASE 2 :

Situation where the firms conceal information and actions from consumers, i.e., asymmetric information is there in the market.

Assumption **:**

The total fixed cost (TFC) incurred by firms in both cases is the same.

CASE 1 :

Assumptions **:**

Cost incurred on R & D = C_{RD}, $C_{RD} = C_{RD}(Q)$
where, Q = quantity produced

Cost incurred on Patent = C_{PA}, $C_{PA} = C_{PA}(Q)$,
where, Q = quantity produced

Cost incurred on Manufacturing = C_{MA}, $C_{MA} = C_{MA}(Q)$,
where, Q = quantity produced

Cost incurred on Registration = C_{RE}, $C_{RE} = C_{RE}(Q)$,
where, Q = quantity produced

Cost incurred on Selection = C_{SE}, $C_{SE} = C_{SE}(Q)$,
where, Q = quantity produced

Cost incurred on Promotion = C_{PR}, $C_{PR} = C_{PR}(Q)$,
where, Q = quantity produced

Since, the consumers are fully informed in this market, the firms do not have any scope to conduct any kind of unethical activities. So, C_{PA}, C_{SE}, C_{PR} have a pretty small value.

Therefore, total cost incurred by a firm is :

$$TC(Q) = C_{RD} + C_{PA} + C_{MA} + C_{RE} + C_{SE} + C_{PR} + TFC$$

CASE 2 :

There is asymmetric information in this market and therefore, firms either over-inflate costs or costs soar up due to the unscrupulous and unethical hidden activities that firms undertake to combat competition in the market.

Cost incurred on R & D :

Firm's record : US$ 350 – 500 million
Estimates by WHO : US$ 30 – 160 million

Therefore, amount of inflation : 312.5% - 1166.7%

Mean amount = (312.5 + 1166.7) / 2

= 739.6%

Let us assume that the each firm inflates their R & D cost by the mean amount.

Hence, the inflated cost on R & D is :

$$C_{RD}^{1}(Q) = C_{RD} + (739.6 / 100) * C_{RD}$$

$$= (839.6 * C_{RD}) / 100$$

$$= 8.4C_{RD}$$

This implies, $C_{RD}^{1} > C_{RD}$.

Thus, on an average, firms actually do project their R & D costs as 8 – 9 times the actual amount. And, the effect of this artificial inflation is felt directly on the price the firms charge.

Cost incurred on Patenting and Registration :

Firms actually bribe and literally buy off the officials responsible for granting patents and legal registrations, as otherwise, potentially dangerous drugs , such as Vioxx, would never have got a clean chit. And, as expected, the actual amount spent on bribery is highly confidential.

Therefore, let us assume that the amount spent in bribing the patenting authorities is α% and that spent on the registration authorities is β%.

Thus, cost incurred on patenting after bribing is :

$C_{PA}^{1}(Q) = C_{PA} + \alpha C_{PA}$

$= C_{PA} (1 + \alpha)$

This implies, $C_{PA}^{1} >> C_{PA}$ **as** α **is very high.**

And, cost incurred on registration after bribing is :

$C_{RE}^{1}(Q) = C_{RE} + \beta C_{RE}$

$= C_{RE} (1 + \beta)$

This implies, $C_{RE}^{1} >> C_{RE}$ **as** β **is very high.**

Cost incurred on Manufacturing :

Firms artificially inflate the cost of manufacturing as well. But, no definite data is available as independent surveys have not as yet been able to unveil the cleverly concealed actual cost figure.

Therefore, let us assume that the amount of artificial inflation is γ%.

Thus, the artificially inflated cost of manufacturing is :

$C_{MA}^{1}(Q) = C_{MA} + \gamma C_{MA}$

$= C_{MA} (1 + \gamma)$

This implies, $C_{MA}^{1} > C_{MA}$.

Cost incurred on Selection, Procurement :

Here, bribery occurs at the levels of the concerned Regulatory authorities at Govt. and in NGOs. Increased commission is offered to distributors, pharmacists and also to medical representatives, in the form of incentives.

Let us assume that the amount spent on bribes and extra commissions is δ%.

Therefore, cost incurred on selection is :

$C_{SE}^{1}(Q) = C_{SE} + \delta C_{SE}$

$= C_{SE} (1 + \delta)$

This implies, $C_{SE}^{1} > C_{SE}$ **as** δ **is fairly high.**

Cost incurred on Promotion :

Annual expenditure on Direct-to-consumer-advertisement (DTCA) = US$ 0.18 million
Annual expenditure on gifts to doctors = US$ 1.5million
Annual expenditure on free samples = US$ 0.72 million
Annual expenditure incurred to train primary care medical representatives = US$ 31.9 million
Annual expenditure incurred to train secondary care medical representatives = US$ 25.3 million

Therefore, total amount spent on promotion annually = US$ 59.6 million

Thus, ultimate cost incurred on promotion is :

$$C_{PR}^{1}(Q) = C_{PR} + 59.6$$

This implies, $C_{PR}^{1} > C_{PR}$.

Therefore, total cost incurred by a firm in this market is :

$$TC^{1}(Q) = C_{RD}^{1} + C_{PA}^{1} + C_{MA}^{1} + C_{RE}^{1} + C_{SE}^{1} + C_{PR}^{1} + TFC$$

$$= 8.4C_{RD} + C_{PA}(1 + \alpha) + C_{RE}(1 + \beta) + C_{MA}(1 + \gamma) + C_{SE}(1 + \delta) + C_{PR} + 59.6 + TFC$$

This implies, $TC^{1}(Q) >> TC(Q)$.

That is, $MC^{1} > MC$

In perfect competition, $P = MC$

Therefore, $P^{1} > P$

The inference is, therefore, that the price of drugs in a "perfectly" competitive market is increased due to the influence of asymmetric information.

EFFECTS

The effects have already been discussed in piecemeals scattered in the discussions of monopoly as well as asymmetric information.

Let us summarise them now.

The DIRECT EFFECT on price of the drugs is by way of addition of unnecessary expenditure incurred by the pharmaceutical companies together with addition of fictitious amounts not incurred and also addition of unlawful profit margins.

If we consider the stages of marketing medicinal products, as described herein before, we can sum up unnecessary and wasted expenditures as follows :

1. **Expenditure incurred by failed R & D and clinical trial,**

2. **Corruption involving all unethical and unlawful payments :**
    a. **bribes**
    b. **cost of influencing concerned authorities at various levels**
    c. **excessive commission to distributors and pharmacists**
    d. **other offers to allure distributors and pharmacists**
    e. **cost of gifts to doctors**
    f. **cost for manufacturing and packaging of free medicine samples**
    g. **sponsorship of various types as described above**
    h. **emoluments of medical representatives**
    i. **cost of publication and distribution of reading materials and advertisements in journals etc.**
    j. **cost of DTCA.**

Inflated costs projected by the pharmaceutical companies is mainly centered around R & D and clinical trial. Firms often add imaginary figures for R & D and clinical trial, even when the product was not formulated in their laboratories. The cost of R & D and clinical trials are almost always over-inflated, when those are actually done in the laboratories of the firms. Addition of these fictitious amounts to the price of medicines causes unusual hike in their price.

Excessive profit is the result of monopolistic market. TRIPS allows constitution of such market, ballooning, thereby, the price of drugs, including the life saving and essential drugs.

Price of medicinal product has direct bearing on cumulative treatment cost. Higher the price of medicines, higher will be the treatment cost. Annual cost of therapy for chronic illness in USA has been found to be increasing from *US$ 33 in the year 2000 to US$ 68 in 2006* for 193 widely used branded drugs.

Indirect effect on prices are no less important. These are primarily the resultants of health hazards caused by the unscrupulous activities of the pharmaceutical firms described herein before.

Though apparently health hazard is a medical subject, but it has immense and far reaching economic effects too. Health hazards caused

by irrational and / or faulty treatment results into additional treatment cost for treating the health hazards created. It also causes decreased man-hour in work places, resulting into reduction in income of the family, and thereby, the nation.

Prolonged morbidity causes cumulative increase in treatment cost, loss in man-hour in work places and further reduction in income.

In extreme cases, health hazards may end fatally. A valuable life is thus lost forever, causing irreparable economic loss to the nation.

Therefore, be it direct or indirect, unscrupulous activities of the pharmaceutical firms results great loss in national economy of our country.

PROPOSED REMEDIES

'Prevention is better than cure'- the dictum holds good in every sphere of life. But we need some strong treatment procedures also, which are required when the disease sets in breaking or bypassing the barrier of prevention.

We should think on the issue of price of medicinal products and, thereby, of treatment cost in our country with our country's perspective and must not follow the foot-steps of the industrialized countries. We should think of Indianised methods which will suit the socio-economic, educational and cultural aspects of our people. Every country acts for the benefit of its people. The behaviour of the companies (supported by their governments) are no exception. We should act for the benevolence of our people while framing the preventive and curative measures on the issues under discussion.

Before we begin the discussions of the possible measures, we must bear one point clearly in our minds that, it is the Governments – both Union as well as State Governments, that must take the initiative and must bear the responsibilities of preventive and curative measures, because, the measures are mostly related to policy making and implementing. Legislature plays a great role in the issue. And finally should come the NGOs and common people.

To take up the problems serially, we should take up the problem of monopoly first. In fact, the pharmaceutical giants of three countries – USA, Japan and Germany hold overwhelming major share of the global drug market. A nexus / cartel of those few giants – holy for the companies and unholy for the vast majority of world population, has, practically, formed a monopoly in the pharmaceutical market of the planet. These companies are so powerful and wealthy that they have even practically have bought up the entire US Congress. The moves taken by the developed countries in WTO in the form of TRIPS, under the

disguise of R & D, are all for the benefit of those handful of companies, and thereby, of the ruling parties and of the countries and their people at large.

Doha Declaration has allowed the southern countries of the world some space to breathe. India should take fullest advantage of the relief allowed by the Doha and other Declarations.

The first and foremost task which Indian Government must look at is the formation of a concrete and full-proof policy – both in relation to medicinal drugs as well as to businesses and industries related to it.

A comprehensive list of essential drugs necessary for tackling all disease conditions – trivial to catastrophic, in our country, has to be finalised and updated regularly. The list is long overdue. Shamefully, many of the miniscule countries in our neighbourhood have made such lists and have taken necessary actions based on the said lists. The life saving essential drugs should be segregated in the list.

Now there should be legislation using Compulsory Licensing clause of WTO Agreement under Doha Declaration, allowing Indian companies to produce generic drugs of all the life saving and majority of, if not all, of the other essential drugs. It is a matter of relief that majority of the drugs in WHO list of Essential Drugs is already out of patent protection period of 20 years. Thus manufacturing of their generic counterparts is no longer forbidden. Indian Govt. must take necessary steps to allow newer essential and life-saving drugs to be marketed under subsidized price. The companies holding the patents, must be instructed to market their products at a subsidised price fixed by the Govt. in accordance to their cost of production + marketing + legitimate administrative cost + rational profit + an additional nominal incentive for their R & D activities. It is to be realised by the pharmaceutical giants that even a very small amount of incentive will ultimately become an enormous sum as the market in developing and underdeveloped countries is too large compared to that of the developed countries. This is a daunting task where the Govt. will have to find out through its own agents, the actual costs incurred. Both this effort as well as fixation of legitimate administrative cost, excluding unethical costs of corruption, and fixation of rational profit margin will expectedly face a stiff resistance from the handful of pharmaceutical giants. But, the Indian Govt. will have to fight this resistance very strongly and authoritatively for the welfare of the people.

Legislation to market essential drugs in non-proprietary names is another important step, which the Government should take. A bouquet of lifesaving and essential drugs available in pharmacies at a very low price, under no brand / generic name, will not only be a boon to the society in the form of a drastic reduction in cost of treatment, but will prevent many unethical, "novel" and spurious medicinal products from flooding the market. The number of drugs available in the Indian market currently will go down from 300,000 to somewhere in between 400 to 500.

Prompt banning of non-essential and spurious drugs, ensuring their immediate withdrawal from market, is another vital function of the government. Regular updating of the international scenario and global recommendations about medicinal products is of utmost importance. Quick action is of paramount importance. Even in country like USA, where action is much faster than in India, a drug named Vioxx took not less than 40,000 lives and made another 48 to 80 thousands crippled with heart attacks. Such catastrophes should be prevented, or, at least, diagnosed early.

Another alternative way is to allow perfect competition for all the medicinal products with the generic producers. An argument against allowing a competitive market may be that R & D will dry up considerably. But, it is to be noted that contrary to the propaganda made by the pharmaceutical giants on the issue of R & D being carried out in their laboratories, many of the patented medicinal drugs are not actually formulated in the laboratories of the pharmaceutical companies. Products created in public or public-private joint venture laboratories or in the laboratories of universities and educational institutions form a substantial bulk of drugs finally being launched. In fact, majority of the products produced by R & D in various laboratories of pharmaceutical companies cannot pass different phases of drug testing – only 15 – 20% of the drugs designed or created by the firms themselves finally enter the market. Furthermore, more than 80% of those finding entry into the market have either no additional efficacy or cannot be labeled as innovative products. Thus, the claim of enormous contribution of those companies in drug generation for the human race is largely a myth.

Moreover, it has been established that from the large sale of life saving drugs, any company can earn much more than their claim of investment in R & D – even their highly inflated figures are adequately covered up with rational profit margin.

The Indian Government has a role to play here. It can move a proposal in the WTO for making a cartel of national governments of all the countries and make a resolution that, the pharmaceutical companies will not be allowed to make unethical profits. As the manufacturing costs of various medicinal products vary between 10 & 30% of their market price, and as the marketing costs range between 30 – 40% of the same, addition of a rational profit should be less than half of the price of medicinal products globally. Government may levy a tax, based on capability of the people . The price of the drugs will still remain around half of the present price, resulting into sufficient rise in the welfare to the society. The amount of tax collected should be pooled to a central authority – say, under WHO and / or UNICEF, who will take care of entire R & D globally through public / private-public partnership laboratories or in University or educational institutional laboratories. This will not only save the cost of R & D, but, higher incentives for research workers will attract better

students to teaching and research work from the clutches of corporate sector.

But, a perfectly competitive market is not a bed of roses. To gain supremacy in the market and to again create a sort of monopoly exploiting the loopholes of rules and regulations, the companies can and do adopt a whole lot of unscrupulous measures. Here, apart from Governments, who play the major role, Non-Governmental Organisations and people themselves should play important roles. The problems of adverse selection and moral hazards have to be dealt with collectively, with Union and State Governments leading the bunch.

Legislation to stop offering gifts and free samples to medical professionals, is easy. But, stricter legislation, involving various funding activities, is necessary, along with regular vigil involving taxation authorities.

Incorrect information in various areas of pharmaceutical business can be imposed heavy to super-heavy monetary penalties. Strict vigil for these irregularities and setting up of high standard, are the duties and responsibilities of Governments.

A dilemma is bound to crop up in relation to banning appointment of medical representatives. India alone employs some 40,000 medical representatives. 40,000 families cannot be made jobless overnight. This will surely require stepwise actions. Restricting their activities, as has been done in various medical centers in the industrialized countries, like banning meeting of representatives with medical professionals in hospitals / nursing homes, can be the initial steps. In addition to this, banning of the aforesaid activities of the pharmaceutical companies, is expected to curb unethical marketing activities of the companies to a large extent. Gradually, the practice of appointing medical representatives has to be abolished to save the entire world from unscrupulous influence of pharmaceutical industry on medical profession. Health of mankind cannot be compromised for the interest of a handful of industrialists. It is to be noted that medical representatives serve no constructive purpose to medical profession and their positive role, if any at all, can easily be replaced in many other transparent ways.

Another loophole – the direct to consumer advertisement, popularly termed as DTCA – has to be plugged. TV ads are not only very costly, adding unnecessarily to product price, but also a powerful popular audio-visual medium to misguide the common people. In these ads, generally, the positive aspects of the products are over-emphasised, concealing the negative aspects. This often leads to incorrect over-the-counter selection of drugs. Thus, using asymmetric information to influence consumers should be made a criminal offence.

Extremely stringent quality control of medicinal products is the basic duty of every Government – our Government is no exception. Till now,

lackadaisical approach of our Government has allowed unscrupulous activities to flourish in as much as WHO had to comment recently that 'about 35% of drugs available in Indian market is no better than talcum power and at least a fifth of it contains harmful chemicals'. No wonder 300,000 drugs are available in India as opposed to 300 essential drugs listed by WHO.

But a million dollar question remains : ' who will bell the cat?' The entire Government machinery can be purchased by the super-powerful and extra-rich pharmaceutical giants.

Then what is the treatment of this apparently incurable disease of Indian society ? There are certain other groups who can keep the Governments on their toes. One must ask the question to the Government of India : If countries like Mozambique can take appropriate measures, if Bangladesh, Sri Lanka, Bhutan can do it, then why not India?

Courts of Law have a vital role to play. Highly alert intelligentsias of a country can bring about renaissance. Legislature can whip the Government to run in correct course. So can the NGOs. Though these are not free from the danger of the gangrene that has eroded much of the values of Indian society, yet combined effort can bring about the changes. Even a small effort from some corner of the battlefield can change the outcome of the war. One General can fight for the people. But, it is imperative that the people, who are the ultimate sufferer of all corruptions and the ultimate beneficiaries of all the good work, support the gallant General always. It has to be remembered that it is the basic human right for every citizen living on this planet to get basic health care services, including purchasing of medicinal drugs, at affordable prices.

Widespread circulation of information regarding banned drugs, unethical drugs, essential drugs, prices of drugs of various brands, spurious drugs, unethical practices and other relevant information, is the key to involve common people in the war against corruption in pharmaceutical market. Confinement of these information within a small circle of medical professionals – and that too very inadequately, is not going to serve the purpose. We need the Union as well as State Governments to initiate the fight for freedom from unscrupulous activities in the pharmaceutical world. The fight has to be fought ultimately by the people with the help of the Governments, NGOs and educational institutions, because, after all, it is their future.

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