'Medicines for All', the Pharma Industry and the Indian State

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When we consider that expenditure on medicines in India accounts for 50% to 80% of treatment costs, India's pharmaceutical success has clearly not translated into availability or affordability of medicines for all. As part of Universal Access to Healthcare, good quality healthcare should be accessible, affordable, and available to all in need. Providing quality medicines to all – free at the point of service – in all our public facilities is an achievable task. This article estimates the cost of providing free and quality medicines at all levels of public healthcare and offers suggestions on how this can be done.

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There are a few articles of faith regarding healthcare which are gaining increasing currency: good quality healthcare should be accessible, affordable, and available to all in need and the poorest person should get the same quality of healthcare as the richest person. Obviously in India this would be seen as a daydream. But in even the so-called developed economies, except the US, free quality healthcare is a reality with nobody having to pay at the point of service and nobody denied free healthcare.

A major component of healthcare is medicines. In India, research studies show that expenditure on medicines accounts for 50% to 80% of the total cost of treatment. In addition patients end up paying for a variety of tests.

Ironically, the Indian pharmaceutical industry is seen as a success story; and it is indeed so in comparison with most developing economies with the possible exception of China. India's pharma success – currently selling Rs one trillion worth of active pharmaceutical ingredients (APIs) and formulations annually – has given it the title of "pharmacy of the world".[1] This success is attributed, among other reasons to India's process-patent-only-regime for medicines post the Patents Act, 1970.

The irony, and the tragedy, of course is that this success has not translated into availability or affordability of medicines for all.[2] What can be done to provide medicines in all our public facilities especially to the poor? The response of policymakers is akin to the discourse in the issue of right to food and subsidised food for the poor. They have come up with targeted schemes which suffer from disagreement over who should be targeted, what should be the extent of free care, which pre-existing disease conditions should be exempted and how to deal with the potential hazard of the system being exploited by healthcare seekers and givers. The only equitable solution in a country like ours is free healthcare of the same standard, to all. The question that would arise would be: why should the rich get free treatment? Our answer is that except for the very rich and the creamy layer of the middle class, almost everybody else is likely to court impoverishment when faced with critical health conditions. It is in the interests of the poor that the relatively well-off, and the middle class are given access to publicly provisioned healthcare, as this would in the long run ensure quality care. The real rich can look elsewhere if they find it inconvenient to use the public healthcare system. Of course, people with better incomes will have to contribute more by way of taxes, etc.

Even if we do not have a free universal healthcare system in a couple of years, movement towards achieving it must begin. The easiest way to restore faith in the system is to stock quality medicines at all levels of public healthcare.

Cost of Free Medicines

The significant issue here is that of the cost of provisioning free medicines. Our estimates show that it will cost the central and state governments around Rs 30,000 crore per year if medicines are given free to all from the primary to tertiary levels, subject to various assumptions. A recent study by Gupta et al[3] estimates the cost to be Rs 33,546 crore. We give the details of our estimate in Annexure 1 (p 50).

Four aspects must be looked at to ensure that the system does not work at cross purposes:

- Restrict the list of medicines available in this country to essential medicines. The current National List of Essential Medicines (NLEM 2003) and WHO's Model List (2010) have around 350 medicines. This can be increased to 500 to include medicines for rare conditions and unnecessary fixed dose combinations and drugs of doubtful or no value can be removed.
- Price regulation of all these medicines.
- A national vaccine policy to regulate the entry of new vaccines as also in the Expanded Programme on Immunisation (EPI).
- Proactive use of Trade Related Aspects of Intellectual Property Rights (TRIPS)

flexibilities including issue of compulsory licences on patented drugs that are high priced and/or are not easily available.

Needless to say, action and regulation on other unethical practices endemic to the pharmacy scenario in India would also help. For instance, incentives to doctors by way of drug promotion; the "cut" practice by doctors,[4] laboratories, CAT scan centres, etc. The professional medical associations like the Indian Medical Association (IMA), the Indian Association of Physiotherapists (IAP), the Federation of Obstetric and Gynaecological Societies of India (FOGSI), the Pharmacy Association, and the Medical Council of India (MCI), among others, must also act in convergence with the above objectives.

Availability of Medicines

Two remarkable attempts, among half a dozen, to make medicines available and affordable have been those by the Tamil Nadu Medical Services Corporation (TNMSC)[5] and the ones at Chittorgarh and Nagaur districts.[6] The former has attained a level of stability though it probably has its share of critics. Its strength lies in the rock bottom low prices at which essential medicines are procured, and a high degree of transparency in the procurement and related operations. It supplied about 270 drugs in 2007-08 as per its essential drug list (EDL) with 21 fast moving drugs accounting for 80% of its procurement budget. It also had 322 "specialty" drugs – out of which 10 drugs accounted for 85.6% of the budget and one – Temozolamide Caps – for 52%. The TNMSC system services all levels of care. The patient does not have to pay for these drugs[7] which are available only through the government health system.

In the Chittorgarh district and Nagaur district models, the drugs are available at the district hospital levels at the *retail* level as well through a series of retail shops run by the government cooperative set up for the purpose. The above poverty line (APL) patients have to pay for the medicines. Any user outside the system could also access these medicines at the same low prices from the generic shops retailing these at various places in the district.

The system runs on a 30-day credit from the suppliers, with the provision for returning unused medicines, with no working capital from the district administration. The 20% margin on the procurement prices takes care of the overheads. Suppliers are mostly well-known companies quoting much lower prices for the district administration (Table 1). It does not reach out to the primary health centres (PHCs) however. Most importantly, the initiative in both these districts was taken by an IAS officer and collector Samit Sharma, who is a paediatrician by training. A tribute to the effectiveness of these efforts is the sale of generic drugs at these prices by other private retail pharmacies in Chittorgarh who put up hoardings to announce the availability of generic medicines (see also Tables 1 and 2). The Rajasthan government has announced free medicines for all in all the government facilities from 2 October 2011 on the lines of the TNMSC, with Sharma now heading this effort.

What can the rest of India's public healthcare system learn from these experiences? The major lesson is that the public health system can deliver given appropriate leadership and political will. Indeed bulk formulation suppliers in Assam complained to this author and his colleagues that the offtake of bulk formulations have fallen in recent years, because of free supply of drugs by the National Rural Health Mission (NRHM) programme. Indeed the pharma trade in Assam is looking forward to the day when the current state health minister – whose zeal is seen as the cause – will step down or lose his ministerial berth even as the traders are hoping that the NRHM will not get an extension.

What will happen to the pharma sector in India in the event of full-scale restructuring and price regulation? Certainly there will be a shake out with perhaps some of them even deciding to shut shop since there will be no free rides to the bank thanks to overpriced, irrational medicines and fixed dose combinations (FDCs). The marketing expenses of these companies will decrease unless they end up spending more on product differentiation of the same essential drug – that is one company claiming their generic product is superior to that of the competitor. The number of retail pharmacies will also come down as the retail trade will not be a money spinner, at least in the short run. In the medium and long run, sales may pick up if some retail outlets are contracted to *provide* and not *sell* medicines and as access to government provisioned healthcare

Table 1: Comparison of Chittorgarh, TNMSC Procurement Prices and Retail Market MRPs

Generic Name of Drug (1)	Unit (2)	Chittorgarh Tender Rate (Rs) (3)	MRP Printed on Pack/Strip (Rs) (4)	TNMSC Prices 2010-11 (Rs)* (5)
Albendazole tab IP 400 mg	10 tablets	11.00	250.00	4.62
Alprazolam tab IP 0.5 mg	10 tablets	1.40	14.00	0.45
Arteether 2 ml Inj	1 injection	9.39	99.00	9.71 for 80 mg per vial
Amylodipine tab 5 mg	10 tablets	2.50	22.00	0.42 for 10 tabs of 2.5 mg
Cetrizine 10 mg	10 tablets	1.20	35.00	0.50
Ceftazidime 1000 mg	1 injection	52.00	370.00	8.77 for 250 mg injection
Atorvastatin tab 20 mg	10 tablets	18.10	170.00	2.30 for 10 tabs of 10 mg
Diclofenac tab IP 50 mg	10 tablets	2.20	25.00	0.63
Diazepam tab IP 5 mg	10 tablets	1.90	29.40	0.47
Amikacin 500 mg	1 injection	6.95	70.00	6.78

*For similar strengths and pack sizes unless indicated otherwise, accessed 29 April 2011.
Source: Prices in Columns (3) and (4) from Samit Sharma's presentation, July 2009, and websites cited, op cit. Source for TNMSC prices: http://www.tnmsc.com/tnmsc/new/html/pdf/drug.pdf and http://www.tnmsc.com/tnmsc/new/html/pdf/spldrug.pdf

Table 2: Comparison of Chittorgarh Procurement Prices and Printed MRP

Drug Manufacturing Company	Name Given by Company (Brand Name)	Ingredient Name of Medicine (Generic Name)	Rate at Which Drug Is Purchased by the Chemist (Stockist Price) One Injection	Rate at Which Drug Is Sold to the Customer (Printed MRP)
Cadila	Amistar 500	Amikacin 500 mg	8.00/-	70/-
German Remedies	Amee 500	Amikacin 500 mg	8.00/-	70/-
Wockhardt	Zekacin 500	Amikacin 500 mg	9.90/-	70/-
Alembic	Amikanex 500	Amikacin 500 mg	8.22/-	64.25/-
Intas	Kami 500	Amikacin 500 mg	8.13/-	60/-
Unichem	Unimika 500	Amikacin 500 mg	7.80/-	72/-
Ranbaxy	Alfakim 500	Amikacin 500 mg	8.50/-	70/-
Cipla	Amicip 500	Amikacin 500 mg	7.42/-	72/-

Source: Samit Sharma's presentation, July 2009, and websites cited, op cit.

becomes near universal. Many of them will attempt to promote ayurvedic and herbal products, hoping that there will be no price and other regulation on these. Many companies will diversify into biologics and vaccines and of course focus on exports. It is here that the government of India could pitch in with funds for R&D of useful drugs for the national scenario, prize funds for innovation and related activities.

Price Regulation

That price regulation in some form is essential is now accepted in much of the literature and in practice. Most advanced "free market" economies have some form of price regulation/subsidy/reimbursement schemes.[8] The Indian pharma formulations industry is characterised by wide-ranging prices for the same product and high profits, apart from marketing and selling unnecessary combinations. Our analysis showed that more than 60% of the top-selling 300 drugs which accounted for nearly 80% of the retail sales are not to be found in the national essential drug list. There are also other ironic consequences due to susceptible users making decisions in distress and out of ignorance. Often, these decisions are taken on the "advice" of prescribers, and due to the "marketing" efforts of companies – called asymmetry by our economists. As a result, the costlier versions of the same drugs are bought more, and irrational combinations sell more because the doctor prescribes them. We have discussed this elsewhere in detail.[9] Tables 3 and 4 (p 46) as also Tables 1 and 2 make the price distortions clear. Collectively it qualifies as a market failure – in the sense that much of the intended clientele is left impoverished after buying India's modern medicines, or worse cannot afford to buy the medicines prescribed, illustrating the classic Indian descriptive metaphor (also witnessed in the food sector) – "sitting on the banks of the Ganga, yet thirsty". It is not a failure if one compares these prices to international prices of medicines, especially the HIV-related medicines. In fact international civil society acolytes of India's pharmacy prowess see the low prices of HIV medicines here as a triumph of the market. The collateral fallout is an interesting phenomenon: local predators are viewed as saints abroad.

Several government committees have commented on the wide differences and high prices within India – though they do not term it a market failure (see Box).[10]

Some questions need to be clarified. Will companies have the freedom to make other medicines – otherwise rational, me too ones – in the post-Universal Access scenario? Following the experience of National Institute of Clinical Excellence (NICE) in the UK, we are tempted to suggest that pharma companies can make and even sell them as long as they are rational (to be decided by the Drug Controller General of India). However, only those drugs will be reimbursed by the government (or an autonomous designated body like, say, an Universal Access to Health Corporation) which are in the government list of reimbursable drugs.[14] But then India is not the UK. We will have to deal with the formidable capacities of the Indian companies to lobby for their products. So all things considered it is preferable to have only a restricted list (the 500 molecules alluded to before) which would be licensed for manufacture and/or marketing in India. India however needs an equivalent of the NICE.

The question of "what will we do for R&D for new drugs" has to be confronted head on but more creatively. R&D funding for new drugs[15] will have to be seen as part of a larger national innovation policy with the clear understanding that Indian pharma companies will work jointly with the government to discover new drugs for conditions that are relevant to India/third world. The policy should also envisage universities working on basic research.[16] Those Indian pharma companies who want to plough their own furrows on R&D must also be encouraged to do so. One thing however is clear – making the patenting of publicly funded research mandatory will not result in quality R&D per se.[17]

The other issue is the carrot often dangled by the Indian pharma lobbies like Indian Drug Manufacturers Association whenever such discourse takes place. They offer to supply all the medicines required by the state and central governments free or at the TNMSC prices. The quid pro quo is "non-interference" especially in matters of pricing. However, this will not work because (a) it is difficult to regulate, manage and morally justify such vastly different prices in the same country to the middle

Box 1: Some Recommendations from Select Committee Reports

The report of the Standing Committee on Chemicals & Fertilisers, 2005-06, Lok Sabha observes:[11]

The Committee's examination revealed that though, there is a provision that a strict watch will be kept on the movement of the prices and the government may determine the ceiling levels beyond which increase in prices would not be permissible, this provision has seldom been applied. In this context, some of the state governments have also informed that when the cases of high prices of anti-cancer drugs, antibiotics, nutraceuticals and cetrizine were referred to the National Pharmaceutical Pricing Authority (NPPA), the latter conveyed its helplessness in curtailing the high prices. The Committee are unhappy over this unsatisfactory state of affairs and desire that the situation should be remedied forthwith. They, therefore, recommend that for the category of drugs for the same therapeutic use, the government should determine a reasonable ceiling beyond which increase in prices may not be allowed.

Draft Pharmaceutical Policy 2006 (hereafter the draft policy)[12]

All 354 drugs in the National List of Essential Medicines 2003 (354 drugs with formulations of specific strengths numbering about 663 excluding exemptions) would be brought under price control. This is in addition to the existing list of formulations of 74 drugs.

Department-Related Parliamentary Standing Committee on Health and Family Welfare, August 2010[13]

34 One option for making available affordable medicines put forth before the Committee was to cap the profit margin of all medicines irrespective of whether they are under DPCO or not. This step would do away with the need of monitoring prescriptions, identifying the manufacturers supplying low-priced medicines and without any need to prefer generic over branded products. If fixation of MRP is done by NPPA based on a fair, transparent system keeping interests of all stakeholders in mind nearly all issues on pricing would get resolved. This system is already in vogue in many other fields such as electricity rates, bus and taxi fares, interest rates, insurance premium just to mention a few. Lastly, with the floating of an open tender in the market, all drug manufacturers/stockiest would come forward with the offer of lowest possible rates . . .

36 The committee is, however, of the considered view that given the current ground realities in the country where more than 80% population is dependent on private medical care and nearly 45 crore people live below the poverty line, the most effective and direct approach would be to put a blanket cap on profit margins of all medicines across the board. Medicines are the only item where the decision to buy is not taken by the purchaser but by a third party, i e, the doctor. Therefore, if prescribers and producers join hands and take advantage of a patients' helplessness, only the State can stop them.

class constituency, who may have to buy the medicines or to justify it before the judiciary, if nobody else, and (b) it would in effect translate and be perceived as "sarkari" medicines for the poor; and costly, quality medicines for those who can afford or have access to insurance schemes, etc. Indeed one can see government doctors advising patients to buy "better" medicines from the nearest retail pharmacy. And (c) this would therefore negate the basic premise of equity in health and postpone by a long measure the goal of universal access and same quality of healthcare for all. Its passage through Parliament will also be difficult since MPs would want to know what happens if the private players renege or if the low prices agreed upon do not turn out to be feasible down the line or even within the contracted period. These are not concerns that can be laughed away for this is precisely what happened with the vaccine commitments made by private vaccine manufacturers after the infamous closure of the vaccine public sector units (PSUs) by the

Table 3: Highs and Lows in Cancer Drug Prices

Drug Name	Highest Price	Firm	Lowest Price	Firm
Letrozole 2.5 mg (10 tablets)	1,986	Novartis	60	Hetero
Imatinib 400 mg (10 tablets	41,152	Novartis	3,000	Glenmark
Nozolamide 250 mg (5 capsules)	22,282	Dr Reddys	4,485	Sun
Pemetrexed 500 mg (vial)	73,660	Eli Lilly	11,990	Glenmark
Exemestane 25 mg (30 tablets)	4,315	Pfizer	1,290	Natco

Source: "NPPA Study Finds Huge Gap in Cancer Drug Prices", Joe C Mathew in *Business Standard*, New Delhi, 31 October 2010.

Table 4: Difference in MRPs of LOCOST and Retail Market Brands

No	Name of Drug	Strength	LOCOST MRP	Brand Name and Manufacturer	Per MIMS (December 2008)	Lowest MRP To LOCOST MRP (%)
1	Albendazole tabs	400 mg	Rs 14.85 per strip of 10 tabs	Albezole – Khandelwal	Rs 12.00 per tablets	65
				Combantrin – Pfizer	Rs 14.83 per tablets	
				Nemozole – IPCA	Rs 9.75 per tablets	
				Zentel – GSK	Rs 17.00 per tablets	
2	Amlodipine tabs	5 mg	Rs 3.70 per strip of 10 tabs	Amlodac – Zy – Alidac	Rs 15.10 per strip of 10 tablets	408
				Amlopres – Cipla	Rs 36.86 per strip of 15 tablets	
				Calchek – IPCA	Rs 22.50 per strip of 10 tablets	
				Lama – Stadmed	Rs 15.03 per strip of 10 tablets	
				Myodura – Wockhardt	Rs 15.45 per strip of 7 tablets	
3	Amoxycillin caps	250 mg	Rs 12.50 per strip of 10 caps	Amoxil – Zydus Cadila	Rs 18.60 per strip of 6 capsules	248
				Amoxivan – Khandelwal	Rs 33.00 per strip of 10 capsules	
				Biomoxil – Biochem	Rs 37.73 per strip of 10 capsules	
				Loxyn – AFD	Rs 35.50 per strip of 10 capsules	
				MOX – Ranbaxy	Rs 67.50 per strip of 15 capsules	
				Novamox – Cipla	Rs 65.00 per strip of 15 capsules	
4	Amoxycillin caps	500 mg	Rs 22.00 per strip of 10 caps	Amoxil – Zydus Cadila	Rs 35.40 per strip of 6 capsules	268
				Amoxivan – Khandelwal	Rs 65.00 per strip of 10 capsules	
				Biomoxil – Biochem	Rs 68.17 per strip of 10 capsules	
				Loxyn – AFD	Rs 38.33 per strip of 6 capsules	
				MOX – Ranbaxy	Rs 120.80 per strip of 15 capsules	
				Novamox – Cipla	Rs 48.95 per strip of 6 capsules	
5	Atenolol tabs	50 mg	Rs 4.25 per strip of 14 tabs	Aten – Zydus Cadila	Rs 30.71 per strip of 14 tablets	647
				LONOL – Khandelwal	Rs 27.50 per strip of 14 tablets	
				Tenolol – IPCA	Rs 32.35 per strip of 14 tablets	
				Tenormin – Nicholas Piramal	Rs 40.00 per strip of 14 tablets	
6	Diazepam tabs	5 mg	Rs 1.70 per strip of 10 tabs	Calmpose – Ranbaxy	Rs 22.00 per strip of 10 tablets	823
				Placidox – Lupin	Rs 14.00 per strip of 10 tablets	
				Valium – Nicholas Piramal	Rs 23.00 per strip of 10 tablets	
7	Enalapril Maleate	5 mg	Rs 4.40 per strip of 10 tabs	Ena – 5 – Stadmed	Rs 19.00 per strip of 10 tablets	431
				Enace – Nicholas Piramal	Rs 25.85 per strip of 10 tablets	
				Envas – Cadila	Rs 46.07 per strip of 15 tablets	
				Nuril – USV	Rs 25.00 per strip of 10 tablets	
8	Fluconazole caps	150 mg	Rs 31.25 per strip of 10 caps	Forcan – Cipla	Rs 34.51 per capsules	1,104
				Syscan – Torrent	Rs 41.00 per capsules	
9	Glibenclamide tabs	5 mg	Rs 3.35 per strip of 10 tabs	Daonil – Aventis	Rs 9.00 per strip of 10 tablets	262
				Euglucon – Nicholas Piramal	Rs 8.80 per strip of 10 tablets	
10	Metformin tabs	500 mg	Rs 5.20 per strip of 10 tabs	Glyciphage – Franco Indian	Rs 17.25 per strip of 10 tablets	138
				Walaphage – Wallace	Rs 7.20 per strip of 10 tablets	
11	Diclofenac tabs	50 mg	Rs 3.00 per strip of 10 tabs	NAC – Systopic	Rs 16.00 per strip of 10 tablets	533
				Tromagesic – Themis	Rs 3.15 per strip of 10 tablets	
				Voveran – Novartis	Rs 34.70 per 15 tablets	
12	Paracetamol tabs	500 mg	Rs 3.80 per strip of 10 tabs	Crocin – GSK	Rs 16.50 per strip of 15 tablets	165
				Calpol – GSK	Rs 10.50 per strip of 10 tablets	
				Malidens – Nicholas Piramal	Rs 9.60 per strip of 10 tablets	
				Pacimol – IPCA	Rs 6.30 per strip of 10 tablets	
13	Rifampicin caps	450 mg	Rs 34.50 per strip of 10 caps	R-CIN –	Rs 42.39 per strip of 10 capsules	122
				Rifamycin – Biochem	Rs 59.18 per strip of 10 capsules	
				Rimactane – Novartis	Rs 22.90 per strip of 4 capsules	
14	Salbutamol tabs	4 mg	Rs 1.90 per strip of 10 tabs	Asthalin – Cipla	Rs 5.21 per strip of 10 tablets	109
				Salmeplon – Khandelwal	Rs 2.08 per strip of 10 tablets	

The prices of the other brands were taken from MIMS, December 2008.
LOCOST prices are from January-March 2009 price list. The situation has not changed much in the two years since.

then union Health Minister A Ramadoss. It is also unclear how the numerous players will divide the cake of government supply.

Regulating Vaccines and Biotech Products

The current trend – backed and initiated by the influential Bill Gates among others – is to advocate vaccines for many of the health problems facing the developing world. Indeed it is good to have a cure, and a vaccine, if we could, for say, HIV. But when supply of clean water and food is the solution, why resort to vaccines? If vaccine manufacturers had their way, 54 vaccines would enter India. However our performance with EPI itself is very poor. Full immunisation – BCG, DPT3, OPV3, Measles- was 66% maximum, probably significantly lower in 2008.[18] Table 5 shows the kind of markups prevalent in vaccines since there is no price regulation.

A national workshop of academicians and concerned health activists which met in June 2009 proposed a draft national policy.[19] As the draft vaccine policy points out,

> The choice of which vaccine to give (or not to give), target population, and mode of administration (dosage, schedule, interval between doses, intramuscular or intradermal, etc), are important policy decisions that must be guided by a strong scientific rationale, after wider scientific debate in the country, with rigorous inputs from multicentric field epidemiology, irrespective of whether it has been proven in populations abroad... Combining any UIP (Universal Immunisation Programme) vaccine with any non-UIP vaccine needs rigorous scrutiny and public debate. Other combinations must be proven to be equivalent to or more effective and safer than single vaccines before adoption.[20]

Costs, efficacy and effectiveness are obviously very important especially with the ever present threat of these being introduced in the retail market first followed by the vaccine manufacturer lobby's attempt to conduct "demonstration projects" to universalise them through the public health system. These concerns again are not theoretical and have been discussed, in the context of the HPV vaccine, in this journal earlier.[21]

As regards biologics, it is debatable whether the optimism or for that matter, the high prices are justified (see Box 2). Avastin (or Bevacizumab of Genentech/ Roche, a drug used to treat various cancers, including colorectal, lung, and kidney cancer) extends the life of a cancer patient by a few months. Here is what one industry researcher has to say,

> …the hype (in the western biotech industry) would have us believe that it is a roaring success. Financially this is certainly not the case. The top 2 or 3 companies account for most of the revenues, and just a few years ago it was estimated that the industry as a whole has lost $100 billion since its inception in the 1970s (*The Economist,* 2006). Are these disastrous financial figures compensated by overwhelming medical success? It does not appear so. One of the most well-known biologics is Avastin, used to treat various cancers, which had revenues of $5.7 billion in 2009 (Allison 2010). This extends life by a couple of months (Shaffer 2010). Medically speaking one might well describe Avastin as a qualified success and yet it is one of the blockbusters of the industry. Undoubtedly there are biologics that do a lot of good, especially for certain patients (and, financially for certain companies), but that is not the whole picture.[22]

In any case it is illogical to keep these biotech drugs out of the purview of the Drugs and Cosmetics Act. All biotech drugs are overpriced and there is no price regulation. In fact the regulation of biotech drugs is sought to be moved to the department of biotechnology (DBT) thus moving it out of the purview of drug price regulation too which is currently under the department of pharmaceuticals, ministry of chemicals and fertilisers. In fact, biotechnology is the new sacred cow that has to be given a long rope as the older ones like (the departments of) atomic energy and space lose their sheen.[23]

Box 2: Cost of Treatment with Biotechnology-based Drugs[24]

- Abciximab (antianginal, Eli Lily): Rs 39,480 for a 60 kg man per day
- Epoeitin alfa (Wepox/Wockhardt, Treatment of anaemia of chronic renal failure): Rs 10,200 for 8 weeks for a 60 kg man and
- Rs 1,912 to 11,475 per week for a 60 kg man thereafter
- Interferon alpha-2a (Roferan-A/Nicholas Piramal) used in types of leukaemia: Initial therapy costs of Rs 43,552- Rs 1,30,656, then maintenance therapy costs of Rs 1,06,158- Rs 3,18,474 (6-18 months cost)
- Etanercept (Enbrel/Wyeth) –in severe arthiritis: Rs 18,131 per week of therapy which has to be taken long-term.

Compulsory Licences

Much has been written on using compulsory licence (CL) as a means of promoting generic competition. India's Patents Act provides[25] for it under Sections 84 (if initiated by a private party), 92 (notification by government that a CL needs to be issued for public non-commercial use, national emergency or extreme urgency), 92A (CL for generic exports) and 100 (for government use). Nothing much has been done in this regard in India in terms of using these provisions. Thailand, Malaysia, Indonesia, Cameroon, Eritrea, Zambia, Zimbabwe, Ghana, Mozambique, Ecuador, Brazil, Italy, Canada and Israel, have been far more courageous in issuing CLs despite the perceived strategic vulnerabilities of some of them with respect to the western governments where the principal big pharmaceutical companies are located. India is one of the few countries where issuing CLs for local manufacture is meaningful, because Indian industry has the capacity to back it up by actually manufacturing the drugs so licensed. Also, there are at least a couple of drugs for which a CL initiated by the government would be of use to the HIV patient community at large – for instance, Raltegravir, Etravirine, Rilpivirine, Maraviroc – all useful in the new types of resistant strains of HIV. To that one can add pegylated

Table 5: Difference in Vaccine MRPs and the Prices for Physicians

Vaccine	Constituent Vaccines	MRP in Rupees, 2008 (A)	Price Offered to Physicians in Rupees (B)	Discount in Rupees (A-B)	Percentage Margin of Profit for the Physician (A-B)*100/B
Pentaxim	Diphtheria, Tetanus, acellular pertusis, inactivated poliomyelitis vaccine, Haemophilus influenzae b conjugate vaccine	2,066	1,446	620	42.9
Imovax polio	Inactivated Poliomelitis vaccine	365	280	85	30.4
Tripacel	Component pertusis, Diphtheria and tetanus toxoids	1,211	762	449	58.9
Okavax	Varicella vaccine	1,468	986	482	48.9
Avaxim 80	Hepatitis A vaccine	952	665	287	43.2
TetractHib	Diphtheria, Tetanus, pertusis, Haemophilus influenzae b conjugate vaccine	504	305	199	65.2
ActHib	Haemophilus influenzae b conjugate vaccine	426	251	175	69.7

Source: Lodha, Rakesh and Anurag Bhargava (2010): "Financial incentives and the Prescription of Newer Vaccines by Doctors in India", *Indian Journal of Medical Ethics*, January-March, VII: 1.

interferon (for chronic hepatitis C), a patent granted despite post-grant opposition; and sorafenib tosylate (useful for renal cancer), erlotinib (useful in lung cancer) – the patent-worthiness of the last two is still a matter of dispute in the courts.[26]

There has been a most encouraging "Note on CL" by the Department of Industrial Policy and Promotion (DIPP)[27] of the government of India around July 2010. From what one can discern the matter is likely to be stymied by those in the Indian cabinet who think issuing CLs will send the "wrong signal" to those interested in investing in this country. India does not need foreign direct investment (FDI) in the pharma sector and issuing of CLs would be well within TRIPS provisions, the Doha Agreement and the so-called August 30 provisions. All these are settled matters internationally, with maybe differences in particularities. Likewise the market qua market ideologues in the Indian cabinet, including the respected economist prime minister, despite the accepted wisdom about inherent asymmetries and potential failures of health markets, continue to espouse (or fail to clearly speak up against) TRIPS plus (more than that required by TRIPS) measures. These include: data exclusivity – in bilateral Free Trade Agreements (FTAs); the attempts to derail Section 3d of the amended Patents Act 2005 of India;[28] against border measures proposed on Anti-Counterfeit Trade Agreement (ACTA);[29] against the conflating and clubbing of issues of intellectual property with public health issues relating to issues of quality of drugs under the guise of the WHO-backed International Medical Products Anti-Counterfeiting Task Force (IMPACT); and of late, investment measures in bilateral FTAs being secretly negotiated – notoriously the investor-to-tate dispute settlement provisions.[30]

'Counterfeit' Charges

Unfortunately these efforts are made by the European Union/American governments at the behest of the big pharma lobbies ostensibly to protect their peoples from harmful, spurious, and "counterfeit" products imported from countries like India/China. But they are actually protecting their turf from Indian generics and hence their (western pharma's) own bottomlines. Competition has been elevated to an economic war of attrition and a war by all means fair and foul, including creating trade barriers gift-wrapped in the language of intellectual property (IP) protection, quality and protection of investments. Many international civil society advocates of access to medicines (from the US, EU, South America and Africa) are aghast at their own governments acting as accomplices of the commercial agenda of big pharma and continue to be at the forefront of countering the harmful effects of these newer barriers to cheaper generics.

"If you cannot beat the competition, buy it out" is another popular strategy. Thus at least six major Indian pharma companies have been partially and completely bought over with at least four others having major marketing tie-ups with multinational corporations (MNCs). This trend does not augur well for the health security and

pharma self-sufficiency of India or for the many countries counting on India as the pharmacy of the world. The sooner the government takes measures to stem the easy pickings that home grown drug companies have become, the more hopeful we can be of realising dreams of universal access to healthcare. One can only hope for a shift in the mindsets of those in power to effect the change. Those without access to medicines in India and elsewhere expect it as a matter of human right and entitlement.

NOTES

1 For some reasons not analysed sufficiently, India dominates the formulations market internationally and China dominates the API market.

2 See Sakthivel Selvaraj and Anup K Karan (2009): "Deepening Health Insecurity in India: Evidence from National Sample Surveys since 1980s", *Economic & Political Weekly*, 3 October, XLIV: 40.

3 Narendra Gupta (2010-11): "What It Costs to Provide Medicines to All Sick Persons in India", *MFC Bulletin,* August-January, Issue 342-43.

4 Can be curtailed possibly by spelling out reimbursable costs of each test and diagnostic procedure – assuming we are talking of a universal access system that will specify reimbursable costs to private practitioners.

5 See www.tnmsc.com for latest procurement prices of TNMSC, accessed 29 April 2011. Also, S Srinivasan (1999): "How Many Aspirins to the Rupee? Runaway Drug Prices", *Economic & Political Weekly*, 27 February-5 March.

6 See: Low Cost (Generic) Medicines Initiative, Chittorgarh, at http://chittorgarh.nic.in/Generic_new/ generic.htm. and http://nagaur.nic.in/GMP.htm, viewed 29 April 2011. Also, S Srinivasan (2009): "Too Good To Be True But True: Retail Sale of Generic Drugs at Low Prices by the Government in Chittorgarh District", *Health Action,* September, also in *MFC Bulletin,* October 2009-January 2010.

7 Maulin R Chokshi (2008): "TN Drug Procurement Model", WHO-SEARO.

8 For medicine price mechanisms in other countries, see Chapter III of the *Report of the Drug Price Control Review Committee*, Dept of Chemicals and Petrochemicals, New Delhi, October 1999. For a more recent review of these, see: Sengupta, Amit, Reji K Joseph, Shilpa Modi and Nirmalya Syam (2008): "Economic Constraints to Access to Essential Medicines in India", Centre for Technology and Development and Society for Economic and Social Studies in Collaboration with WHO SEARO. A more recent news item (2011) at "Germany Caps Drug Prices", *Nature Biotechnology,* February, 29 (2).
For other views, see Gregson, Nigel, Keiron Sparrowhawk, Josephine Mauskopf and John Paul (2005): "A Guide to Drug Discovery: Pricing Medicines: Theory and Practice, Challenges and Opportunities", *Nature Reviews Drug Discovery*, 4 February: 121-30. For a review of the use of evidence in the market approval process, reimbursement, and price control mechanisms for medicines and medical devices in Thailand, South Korea, and Taiwan, see Jirawattanapisal, Thidaporn, Pritaporn Kingkaew, Tae-Jin Lee, Ming-Chin Yang (2009): "Evidence-Based Decision-Making in Asia-Pacific with Rapidly Changing Healthcare Systems: Thailand, South Korea, and Taiwan", *Value in Health*, Vol 12, SUP3 [Note(s): S4-S11]. Thanks to Szymon Jaroslawski for these papers.

9 We have discussed this at length in LOCOST (2006): *A Lay Person's Guide to Medicines: What Is in Them and What Is Behind Them* (Vadodara: LOCOST). And also in LOCOST/JSS (2004): *Impoverishing the Poor: Pharmaceuticals and Drug Pricing in India* (Vadodara/Bilaspur: LOCOST/JSS), also available online at: http://www.scribd.com/my_document_collections/2879052 and http://www.scribd.com/my_ document_ collections/ 2474529

10 The Sandhu Committee Report of 2004, the earlier Drug Price Control Review Committee Report of 1999, and a Task Force appointed by the PMO in 2005 and chaired by Pronab Sen from the Planning Commission, the Commission on Macroeconomics and Health 2004, etc, – all have endorsed price regulation of drugs.

11 Recommendations/observations of the Committee, Para 10 in "Availability and Price Management of Drugs and Pharmaceuticals". Seventh Report, Standing Committee on Chemicals and Fertilisers, 2005-06, Fourteenth Lok Sabha, Lok Sabha Secretariat, New Delhi, September 2005.

12 The draft policy had several other recommendations but it was quietly shelved because of opposition from India's pharma industry on the price regulation aspects.

13 "On Issues Relating to Availability of Generic, Generic-Branded and Branded Medicines, Their Formulation and Therapeutic Efficacy and Effectiveness" (Presented to the Rajya Sabha on 4 August 2010) (Laid on the table of the Lok Sabha on 4 August 2010).

14 Ruth R Faden and Kalipso Chalkidou (2011): "Determining the Value of Drugs – The Evolving British Experience", *N Engl J Med*, 7 April, 364 (14). As the authors point out, "Contrary to some reports, NICE has no authority to restrict access – British law mandates only that the NHS provide funding to cover recommended drugs. Nor is NICE responsible for setting drug prices. In the 10 to 15% of cases in which it recommends against providing access to a drug because of poor cost-effectiveness or clinical effectiveness, stakeholders regularly exercise their right to appeal the decision and are sometimes successful. (Roughly 30% of the NICE recommendations are appealed, and roughly 10% of the appeals result in substantial changes to the recommendations.)" Thanks to Sunita Sheel for pointing out this report.

15 For a spirited summary of the arguments against high R&D costs, see Donald W Light and Rebecca Warburton (2011): "Demythologising the High Costs of Pharmaceutical Research", *BioSocieties*, 6: 34-50.

16 There is a vast burgeoning literature on pharma innovation and desirable policies in a post-2005, product patent world, especially on how to use TRIPS flexibilities, how to get around patenting by prize funds, patent pools, etc. The degree of their belief in the sanctity of the TRIPS/WTO system varies and mostly not stated upfront. Nevertheless, see for instance, Joseph E Stiglitz and Arjun Jayadev (2010): "Medicine for Tomorrow: Some Alternative Proposals to Promote Socially Beneficial Research and Development in Pharmaceuticals", *Journal of Generic Medicines,* 7 July: 217-26; and the readable chapter 8 on "A Policy Agenda for IP, Access and Innovation" in T Hoen, Ellen F M (2009): *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health* (Netherlands: AMB). And the more legally researched tract by Spennemann, Christoph and Jerome H Reichman (2011): *Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries: A Reference Guide* (New York, Geneva: UNCTAD, United Nations). To touch base with Indian reality, see Sudip Chaudhuri, Chan Park and K M Gopakumar (2010): *Five Years into the Product Patent Regime: India's Response* (New York: UNDP).

17 See Sara Boettiger and Alan B Bennett (2006): "Bayh-Dole: If We Knew Then What We Know Now", *Nature Biotechnology*, 24: 320-23. Also see Bhaven N Sampat. *The Bayh-Dole Model in Developing Countries: Reflections on the Indian Bill on Publicly Funded Intellectual Property.* UNCTAD-ICTSD Project on Sustainable Development on IPRs and Sustainable Development. Policy Brief Number 5, October 2009. Also David C Mowery, Richard R Nelson, Bhaven N Sampat and Arvids A Ziedonis (2001): "The Growth of Patenting and Licensing by US Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980", *Research Policy*, 30: 99-119.

18 See for immunisation coverage figures for 2008: http://www.searo.who.int/vaccine/LinkFiles/EPI2008/India08.pdf, accessed 29 April 2011.

19 Y Madhavi et al (2010): "Evidence-based National Vaccine Policy", *Indian J Med Res*, May, 131: 617-28.

20 There is another recent draft at the behest of the government that is doing the rounds and that negates this sound principle, inter alia.

21 Sarojini N B, Sandhya Srinivasan, Madhavi Y, Srinivasan S and Anjali Shenoi (2010): "The HPV Vaccine: Science, Ethics and Regulation", *Economic & Political Weekly,* 27 November, XLV: 48.

22 Personal Communication from industry observer and researcher Gayatri Saberwal, 29 April 2011. The citations in the quote refer to the following: "Profitless Prosperity". *The Economist*. 379, 63 (22 April 2006); Allison, M "Avastin's Commercial March Suffers Setback", *Nature Biotechnol*, 28, 879-80 (2010); and Shaffer, C "Pfizer Explores Rare Disease Path". *Nature Biotechnol*, 28, 881-82 (2010).

23 The Draft Biotechnology Regulatory Authority of India Bill 2009 also has the by now infamous clause, Section 63, that proposes imprisonment and fine for anyone who "without evidence or scientific record misleads the public about safety of GM crops". No soft-pedalling of the law here. Space and Atomic Energy – presumably one can 'mislead' and get away to some extent.

24 Figures courtesy Anurag Bhargava, 2008.

25 Section 84 – CLs initiated by generic companies who can apply when (a) the reasonable requirements of the public with respect to the patented invention have not been satisfied or (b) it is not available to the public at a reasonably affordable price and (c) the patent is not being worked. The grant of CLs to competitors such as generic companies can be an effective measure to make patented drugs affordable and available. However, the provisions impose a three-year waiting period from the date of the grant of the patent before a generic company can make an application for a CL.
Section 92 – Notification by central government in the official gazette that a CL needs to be issued for public non-commercial use, national emergency or extreme urgency. After the notification, the patent controller can grant a compulsory license to a generic company so that the drug is made available to the public at an affordable price.
Section 92A – CL to generic company when another country wants to import drugs. This provision is important, as Indian generic manufacturers play a key role in supplying medicines to developing countries with insufficient manufacturing capacity.
Section 100 – Government use licence, which will apply in situations where the government needs to manufacture, procure, distribute and sell the patented drug on a non-commercial basis.

26 "Two domestic drug makers", according to a report in the *Business Standard*, 3 May 2011 (http://www.business-standard.com/india/news/domestic-drug-makers-set-to-invoke-compulsory-licensing-route-by-june/434161/), "Cipla and Natco, are known to have already written such requests to global pharmaceutical MNCs for such a contract to manufacture an AIDS drug and a cancer drug, respectively. Natco's request for permission to manufacture a generic version of cancer drug Sorafenib has been rejected by Bayer. Cipla is awaiting a response from Merck on AIDS drug Raltgravir. The next step, following an unsuccessful attempt to enter into a contract, will be to apply for a compulsory licence….three cancer drugs – Nilotinib, exclusively marketed by Novartis under the brand name Tasigna; Sunitinib, marketed by Pfizer as Sutent; and Bristol Myers Squibb's Dasatinib (brandname Sprycel) – are the other products eyed by domestic pharma companies for compulsory licensing opportunities".

27 See http://dipp.nic.in/ipr-feedback/CL-DraftDiscussion.doc, accessed 29 April 2011. The DIPP of

the Government of India administers the Patents Act 1970, the Trade Mark Act 1999, Geographical Indications of Goods Act, 1999 and Designs Act, 2000. It also coordinates issues relating to World Intellectual Property Organisation (WIPO) in consultation with other ministries. A departmental release of 11 April 2011 clarified, "As the existing legal framework is comprehensive, government has decided that there is no need to issue additional guidelines for the issue of compulsory licences".

28 Internationally acclaimed by developing countries and positive groups as a life-saving measure that prevents evergreening and frivolous patenting, a clause that prevented the product patenting of at least the following drugs after vigorous contestation pre-grant, post-grant: lamivudine/zidovudine (fixed-dose combination); tenofovir (intermediate, salt and pro-drug forms); darunavir polymorph; tenofovir disoproxil fumarate/emtricitabine (co-formulation); imatinib crystalline form; pro-drug of oseltamivir; crystalline adefovir dipivoxil; crystalline adefovir dipivoxil; and valgancyclovir.

29 For instance: See chapter 2 (full text at http://trade.ec.europa.eu/doclib/docs/2010/ december/tradoc_147079.pdf, accessed 29 April 2011) of the released text, dated 3 December 2010, provides for Border Measures in case of all IPRs, not only copyrights and trademarks. It also includes exports; it also includes in-transit consignments under customs supervision. We can all anticipate the effect of these strong border measures on the flow of in-transit generic medicines. These measures are one-sided and there is little recourse for review of decisions or appeal against them by those affected. ACTA ignores and bypasses existing multilateral processes provided like WTO and the World Intellectual Property Organisation (WIPO), and its enforcement level beyond the minimum mandated by TRIPS.

See also European Commission (EC)'s comments on the "Opinion of European Academics on Anti-Counterfeiting Trade Agreement" at http://trade.ec.europa.eu/doclib/docs/2011/april/tradoc_ 147853.pdf, accessed 29 April 2011.

30 "Investor-to-state" dispute mechanism is basically a provision that can enable EU corporations (as well as those of other countries like the US) who qualify as foreign investors to take the Indian government to private arbitration panels over domestic health policies like tobacco control legislations, banning of dangerous chemicals and measures to reduce prices of medicines. Particularly, the tobacco, chemical and pharmaceutical corporations can easily challenge domestic laws and policies to sue and obtain damages of millions of euros or dollars against the Indian government through international arbitral proceedings if their investments (profits) are allegedly impeded by Indian environmental and public health policies and legislation. Source for this formulation: Briefing Note of Delhi Network of Positive People (May 2011): "Investment Provisions in the EU-India FTA: Impact on Access to Medicines" (New Delhi: DNP+).

Annexure 1: Estimating Drug Requirements of India under Universal Access to Health for All

Assumptions:

(1) We have used utilisation figures of the Tamil Nadu government, from the Tamil Nadu budget documents, and its procurement agency the Tamil Nadu Medical Services Corporation (TNMSC). We do not define utilisation but we use it here as some rough indicator of the percentage of total population of the state using the services of the Tamil Nadu public health system where "using" means attendance at an outpatient department per year and/or in-patient services per year when otherwise the person seeking treatment would have had the option to go to the private practitioner/private sector. We also assume for all those who seek health, the facilities are geographically accessible – which is of course not true generally.

(2) Population of Tamil Nadu and India: 7.2 crore and 121 crore (2011 provisional census figures).

(3) Tamil Nadu government drug budget for medicines 2011-12: Rs 142.88 crore out of a total health budget of Rs 4,554 crore (Table 6). There is a bias in TN government policies of late towards tertiary care.

Table 6: Amount Budgeted for Supply of Medicines through TNMSC (2011-12)

Account Head	Amount Budgeted 2011-12 (in Crore)	Source
Directorate of public health and preventive medicine	3.00	http://www.tn.gov.in/tnbudget/demands/d1904.pdf
Directorate of medical and rural health services	61.88	http://www.tn.gov.in/tnbudget/demands/d1902.pdf
Directorate of medical education	78.00	http://www.tn.gov.in/tnbudget/demands/d1903.pdf
Total	142.88	

(4) We add another 25% (liberal guesstimate) for medicine supply under other special programmes for chronic and endemic diseases like TB, malaria, leprosy, HIV, renal problems, cardiovascular diseases, etc. The above total of Rs 142.88 crore will be revised to Rs 178.60 crore.

(5) We also assume that the prescriptions and treatment are by and large rational in the TN government system – so there is none of the private sector waste. Or at best negligible.

(6) We assume from a calculation of N Lalitha of Gujarat Institue of Development Research (personal communication) that the utilisation in Tamil Nadu of public health facilities is around 40% – a figure projected for 2005-06 from NSS 60th round figures (January-June 2004).

(7) Therefore for complete utilisation the total medicine demand would work out to be (Rs 178.60 crore x 100)/40 = Rs 446.50 crore.

(8) For a population of 7.2 crore, it is Rs 62.01 per capita. For India's population of 121 crore, this would be Rs 7,504 crore.

(9) This seems a puny figure, but we need to recollect that these are at TNMSC rates which are very low and are quoted at just above bare costs of manufacture. If India's pharma industry sells medicines at this rate and only these essential medicines at that, they probably will be in a spot of a bother with respect to sustainability and viability. We suggest that the Chittorgarh/ Nagaur figures, which are on the average 3-4 times the TNMSC price, are more realistic. Or like the figures of socially-oriented manufacturers like LOCOST (prices at www.locostindia.com). These rates (that of Chittorgarh, LOCOST et al) will ensure better accommodation for manufacturer's overheads and distribution margins/ overheads of the supply chain. So we will make the above estimate 4 times Rs 7,504 crore that is around Rs 30,000 crore. This figure also is of the same order as that of Gupta et al who use Chittorgarh procurement rates.

(10) Of course, if the Government of India does not rationalise the kinds of medicines produced in India or regulates their prices, we would suggest then that in this business as usual scenario, we will require only Rs 7,504 crore plus 25% margin for retailer-wholesaler, that is a maximum of Rs 9,380 crore: because we expect that some distribution under a universal access framework will still need to be done through private retail pharmacy shops who will retail these low-priced generics as well as other costlier medicines, with the latter being their bread and butter, and jam, as it is currently.