‘Politics is medicine at a large scale’

Medicine is a social science, and politics is nothing else but medicine on a large scale ....

Rudolph Virchow

Our health is also fundamentally defined and determined by processes beyond healthcare ...

Access to Healthcare

Remembering Alma Ata and the Primary Health Care Approach

Abandoned by countries and international agencies soon after the Alma Ata Declaration, continues to be as relevant today as it was 40 years ago.

- ✓ **Comprehensive approach to health**
- ✓ **Integration of different programmes and services**
- ✓ **Equity**
- ✓ **Appropriate' health technology,**
- ✓ **Community involvement in the health care system.**
- ✓ **Human rights perspective by affirming that health is a fundamental human right and by placing the responsibility on governments to act on this.**

Bringing Back the “public” in Health Care Systems

Only an adequately financed public service can break the link between the income of health care providers and the delivery of health care.

Access to Medicines

Access to Medicines
-- why the urgency?

- 2 billion people lack access to essential medicines.
- Improving access to existing medicines could save 10 million lives each year
- 15% of the world's population consumes over 90% of the world's pharmaceuticals.
- Now, more than ever before, when tools to treat medical conditions are available and being developed (or having that potential, yet untapped) rapidly, the inability of large populations to access these tools is a serious human rights issue – in the North HIV/AIDS is a chronic disease, in the South it's a killer disease, the biggest difference being access to antiretrovirals

Whose Obligations?

- States (country Governments) have primary responsibility for enhancing access to medicines.
- States, on the other hand, have emphasised the profound impact - of pharmaceutical companies (often working outside the boundaries of control of a single Govt.) on the ability of governments to realise the right to the highest attainable standard of health for individuals within their jurisdictions.
- Medical Professionals also have a major role in ensuring access by promoting rational and judicious use of medicines

Barriers to Access

Price of Medicines

- Prices constitute the single largest barrier to Access – in most cases if people have the money to buy medicines, the same are available

- Price of medicines vary tremendously across countries and within countries – thus showing how much can be done to lower prices

Price stabilisation and reduction depends on:

- Intervention by the Government through price regulation
- Competition in the market
- Local production
- Taxes and Duties
- State intervention in drug production
- Appropriate Use of medicines – inappropriate use of expensive alternatives in the presence of cheaper therapeutically equivalent alternatives pushes up total treatment costs

Intervention by the Government is more important in LMICs because:

- High prices "cost out" vast sections of the people
- Public Health Investment by Governments is generally lower in LMICs – thus larger numbers have to buy from the market
- Retail sales constitute a much larger proportion of medicines – generally companies negotiate much lower prices for sales to institutions – public, Health Management Organisations, Insurance Companies
- High Prices also compromise ability of resource poor countries to ensure Access
- Interestingly developed countries have much more developed mechanisms for price control and regulation

Equity in Availability of Medicines

- Distribution of medicines so that they preferentially reach the underserved is necessary.
- In practice the reverse happens, thereby promoting further inequity
- Health Systems need to be designed to promote equity in distribution, but actually many Health Systems following the institution based model do the opposite

Monopoly in Drug Production, Sales and Distribution

Major barrier to access – following contribute to it:

- Intellectual Property Rights, especially after signing of TRIPS in 1995 – took away right of individual states to makes special provisions in the case of medicines as regards IPRs
- Technology Transfer and local production is seldom a goal pursued by non-local manufacturers or promoted by country governments – esp. those with minimal manufacturing capabilities

Quality of Medicines

- Sub-standard quality, translates into poor Access and poorer populations are likely to be exposed to a much larger volume of such drugs
- Regulation of Quality is the responsibility of the State, but seldom pursued in countries of the South with necessary vigour
- Companies have the responsibility that they adhere to Good Manufacturing Practices (GMP) and the State needs to lay down the guidelines – this is lacking in most countries of the South

Inappropriate Use of Medicines

- Inappropriate Use pushes up treatment costs – yet promotion of medicines in a particular way distorts use of medicines
- A study in India showed, e.g. that over half of medicines prescribed are either irrational or hazardous or both
- Ideally medicines in an EDL should address 95% of needs – in practice this seldom happens, even in public institutions

Inappropriate R&D

- The IP based system of R&D promotes research in areas where there is maximum profit, not where there is greatest need
- e.g. the last medicine developed for T.B. was introduced 30 years ago, *me-too drugs* (Cox2 inhibitors, ACE inhibitors, H2 antagonists, etc.) proliferate, conferring little therapeutic benefit but logging huge sales
- Alternate models for R&D with public ownership over the final product need to be promoted
- Clinical Trials in developing countries are much more prone to the flouting of promotional norms

Assessment of New Drugs Introduced Between 1981-2000

Category	No.	%
Major therapeutic innovation in an area where previously no treatment was available	7	0.31
Product is an **important therapeutic innovation** but has certain limitations	67	2.96
Product has some value but does not fundamentally change the present therapeutic practice	192	8.51
Product has **minimal additional value**, and should **not change prescribing habits** except in rare circumstances	397	17.59
Product may be a new molecule but is **superfluous because it does not add to the clinical possibilities** offered by previous products available. In most cases it concerns a me-too product	1427	63.23
Product without evident benefit but with potential or **real disadvantages**	58	2.57
Editors **postpone their judgements** until better data and a more thorough evaluation of the drug is available	109	4.83

Source: Prescrire

Contributors to Barriers of Access

Global Treaties – Such as that on Intellectual Property Rights

Government Regulation (or lack of) in:

- Production
- Price
- Distribution
- Promotion

Contributors to Barriers of Access

Industry Practices

- Lobbying
- Promotion
- Corruption
- Restrictive Trade Practices

Medical Professionals

- Irrational Use
- Succumbing to promotional practices

Intellectual Property Rights and Access

What are Intellectual Property Rights?

- Intellectual Property Rights are state mandated monopolies
- There are many forms of IPRs – patents, copyrights, trademarks…
- IPRs restrict competition, create artificial shortages of products, and create monopolies
- IPRs arose several hundred years ago to help dissemination of knowledge and reward those producing new knowledge, but now they do just the opposite

Towards WTO – the Uruguay Round of Negotiations

- In 1986 a new round of negotiations was initiated under GATT (General Agreement on Tariffs and Trade) -- the Uruguay Round of negotiations.

- The developed countries introduced a number of issues were hitherto not considered as trade -- Intellectual Property Rights, Investment and Services.

- Especially India was opposed to introduction of Intellectual Property Rights in the negotiations

The Indian story: Dramatic expansion of pharmaceutical industry after 1970

- The 1970 Patent Act, accompanied by other measures to encourage domestic manufacture of medicines, had a dramatic effect on India's pharmaceutical industry and on access to new medicines in the country.

- The research capacity of public sector research institutions was harnessed to develop new processes for manufacture of medicines that were not already patented.

Impact of 1970 Patents Act on introduction of New Drugs in India

Drug	Patented Drug Introduced in Global Market	Generic equivalent introduced in Indian market
Ranitidine (anti-ulcer)	1983	1985
Cimetidine (anti-ulcer)	1976	1981
Norfloxacin (anti-bacterial)	1984	1988
Astemizole (non-sedating anti-histamine)	1986	1988
Acyclovir (anti-viral)	1985	1988
Salbutamol (bronchodilator)	1973	1976
Mebendazole (anti-helmintic)	1974	1978
Ibuprofen (anti-inflammatory)	1967	1973
Lorazepam (anxiolytic)	1977	1978

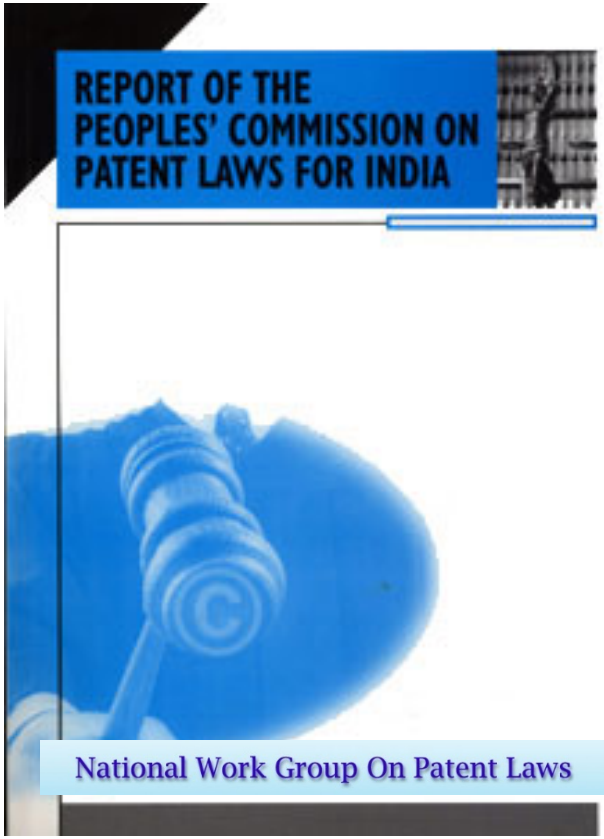
Comparative drug prices in 1991-92 – impact of generic production of patented drugs

(all prices calculated in Indian Rs.)

Drug	Year of Patent Expiry	Dosage and Pack	Price in India	Price in Pakistan	Price in the US	Price in the UK
Norfloxacin (anti-bacterial)	1996	400 mg x 10	39.36	125.50	626.15	252.77
Ranitidine (anti-ulcer)	1995	300 mg x 10	29.03	260.40	744.65	481.31
Enalapril Maleate (cardiovascular)	2000	5 mg x 10	9.00	37.20	230.83	147.97
Acyclovir (anti-viral)	1997	5% cream x 5 g	33.75	363.32	356.74	577.68
Ketaconazole (anti-fungal)	1999	200 mg x 10	43.00	221.96	673.67	157.98
Fluoxetine (anti-depressant)	2001	2mg x 10	29.00	618.76	517.83	562.41

Broken resistance..

- By the beginning of 1989 the resistance by developing countries was broken down.
- Both Brazil and India were plagued by domestic economic problems, and bilateral pressure by the US resulted in the two main hold-outs changing their position
- The negotiations in adoption of the TRIPS agreement in 1994 under the WTO


REPORT OF THE
PEOPLES' COMMISSION ON
PATENT LAWS FOR INDIA
National Work Group On Patent Laws


CPI(M)
FREE
to exploit
nature & people
TRADE
CITU
WTO
Down Down!


Govt.
of
India
must
come
out of
WTO
SUCI
DOWN
WITH
AFRICA
WTO


milana
NO AMENDMENT
WITHOUT
PUBLIC DEBATE
HEALTH AS A
RIGHT
ISSUE


Affordable
HIV/AIDS
TREATMENT
Delhi Network of People living with HIV/AIDS
DNP+
SAVE our LIVES by providing TREATMENT
NO to PATENTS ACT
02/26/2005

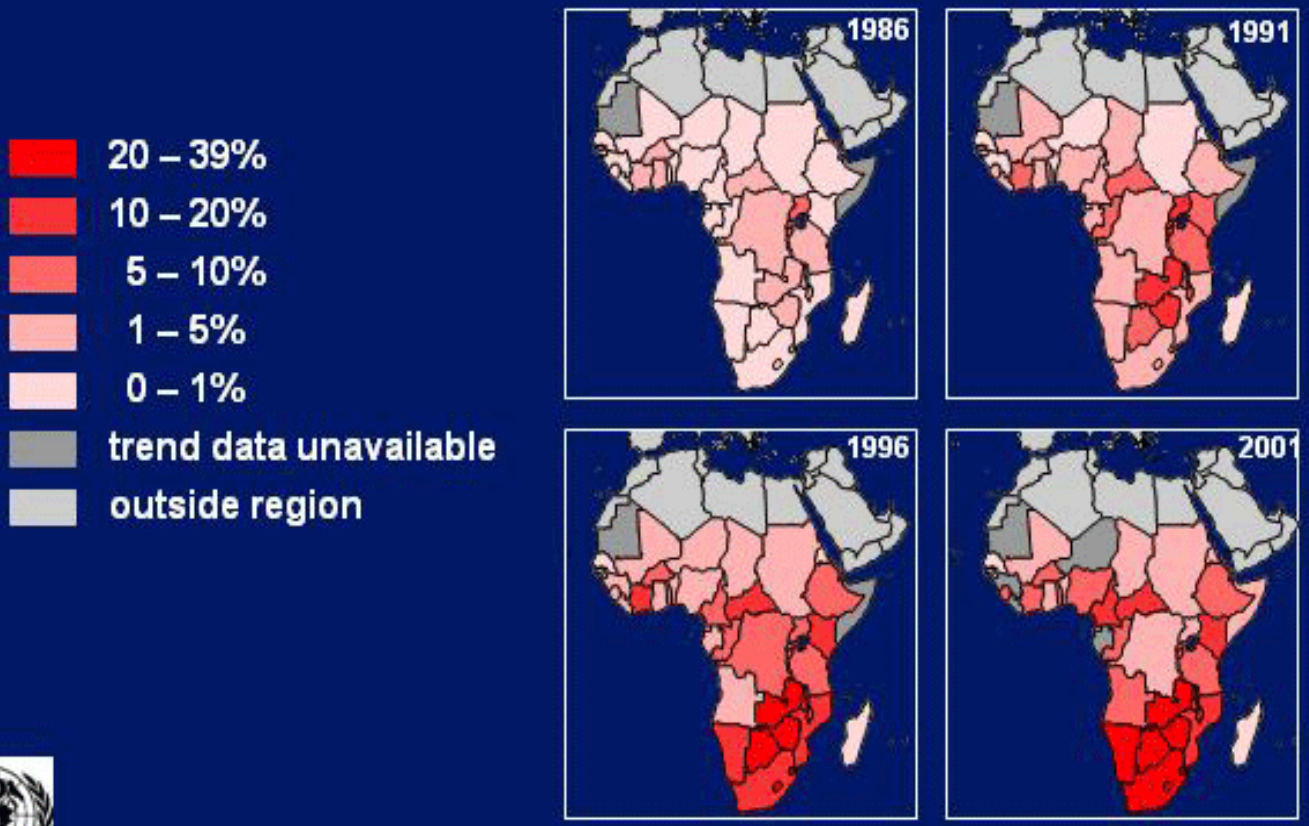
Health Safeguards (TRIPS flexibilities) incorporated in the Indian Patent Act 2005

- Fairly strong **Compulsory Licensing** Provisions and Government Use provisions
- Strong '**patentability criteria**' meaning trivial and obvious inventions cannot be patented
- Strong provisions for **pre and post grant oppositions**

The HIV/AIDS Story

How an Indian Company changed the course of history in sub-Saharan Africa

HIV prevalence in adults in sub-Saharan Africa, 1986-2001

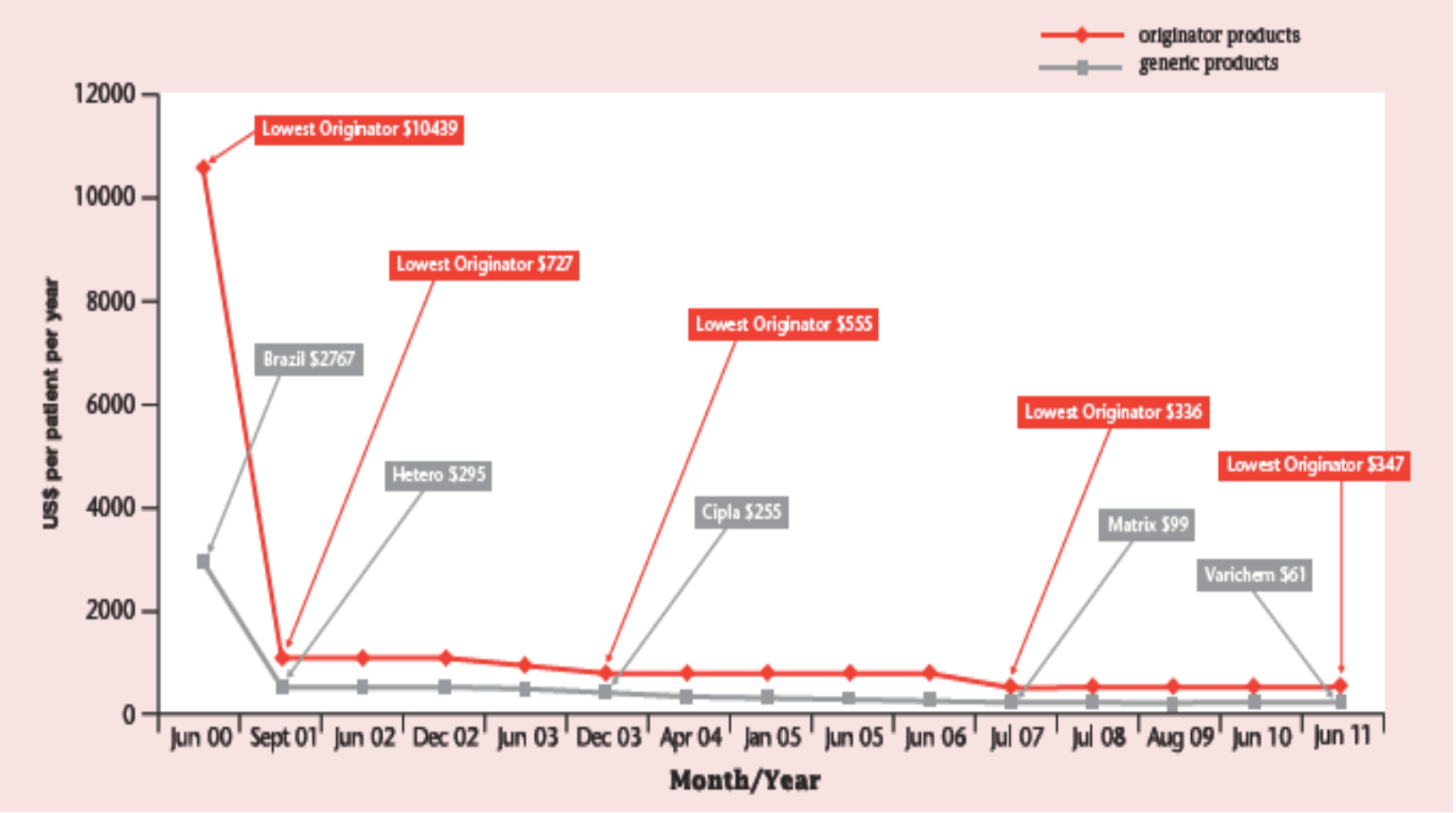


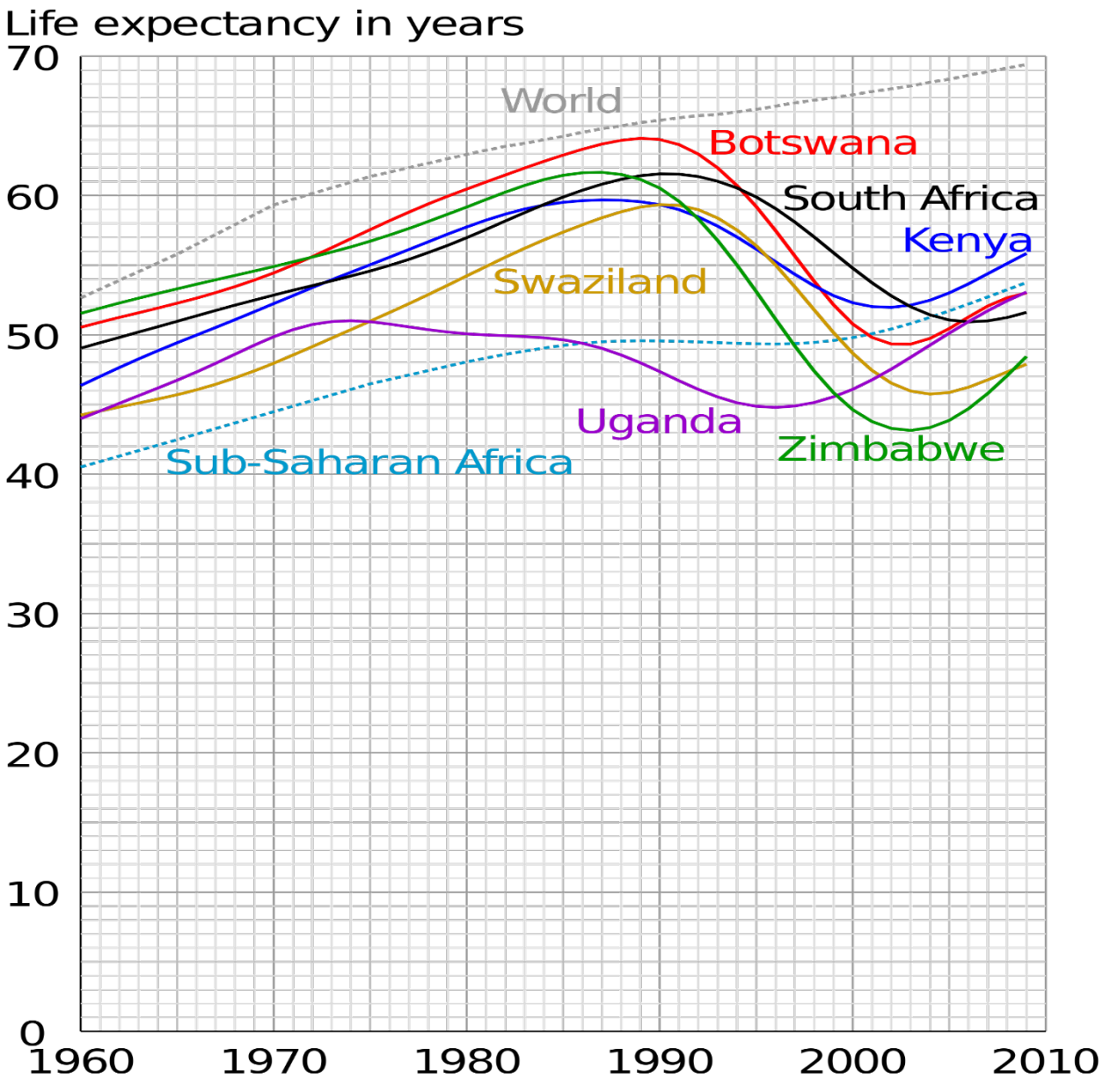
World Health Organization

UNAIDS

Introduction of $350/year treatment by CIPLA

- Cipla's offer of triple therapy in February 2001 was for US$350 per patient per year (against $10,000 offered by MNCs). Current prices for 1st line triple ARV therapy is approx. US$99.




Life expectancy in years
70
60
50
40
30
20
10
0
1960
1970
1980
1990
2000
2010
World
Botswana
South Africa
Kenya
Swaziland
Uganda
Zimbabwe
Sub-Saharan Africa

..the economic benefits of antiretroviral therapy explain 44% of observed growth in per-capita GDP in sub-Saharan Africa between 2004 and 2012

…fast forward to 2014

The Hepatitis C story

How Indian Companies were tamed and failed to deliver

Hepatitis C – looming threat

• Globally, an estimated 160-180 million people harbour the Hepatitis C virus and many of them will eventually die of the infection.

• Each year about half a million people succumb to Hepatitis C infection

• In India there are about 12-18 million people who are infected by the virus and about a 100,000 are estimated to die each year.

• Some countries have extremely high rates of Hepatitis C infection, with Egypt reporting that 14-22% of its population is infected.

Sofosbuvir... the 1000 dollar pill

- Sofosbuvir is one of a new class of drugs that have been launched recently as treatment for Hepatitis C.
- Sofosbuvir is to Hepatitis patients what anti-retrovirals were to HIV/AIDS patients
- But Gilead initially priced its drug at over USD 1,000 per tablet.
- Andrew Hill and others, estimated that the total treatment cost over 12 weeks with Sofosbuvir should be in the range of $68-$136.

Gilead's cash cow…

• In 2013 Gilead Sciences commenced marketing of its new Hepatitis C drug, Sofosbuvir (as Sovaldi).

• Sovaldi's sales in the first quarter of 2014 touched $3.48 billion and it is projected that the 2014 sales of Sovaldi will outstrip that of the biggest block-buster drug ever – Pfizer's Liptor

• Thus Sovaldi's 2014 sales would be more than the entire domestic market for medicines in India.

The ‘Gilead Licenses’..

- In 2014, Gilead acted quickly to preempt the entry of cheap Indian generics by striking a deal with eight Indian generic companies
- Indian generic companies provided voluntary licenses by Gilead, and in return the companies will be restricted by Gilead’s strict ‘anti-diversion’ clause.
- The drug can be exported only to a select list of countries, thus depriving poor patients in a range of High and Middle Income Countries (HICs and MICs) such as China, Brazil, Russia, USA, Thailand, Turkey, Mexico, Ukraine and Georgia.
- Deal was struck when there was no patent on the drug in India and a few months later the patent application was rejected

Restrictive clauses…

•The drug can be exported only to a select list of countries approved by Gilead, thus depriving poor patients in a range of High and Middle Income Countries (HICs and MICs) such as China, Brazil, Russia, USA, Thailand, Turkey, Mexico, Ukraine and Georgia.

•Importantly the deal was struck when there was no patent on the drug in India and a few months back the patent application was rejected (January 2015)

The difference between 2001 and 2014?

- **India moved to a product patent regime in 2005…**

But not just that……..

What else has changed?

- Support to domestic industry as part of public policy has disappeared
- Faced with a stagnating domestic market Indian generics are looking at the markets in the US and Europe
- There is reluctance to use the health safeguards in the Indian Patent Law

So…

Indian generic companies would tend to collaborate rather than confront Big Pharma

Educate
Mobilise
Organise
Change

Thank You!