

# Role of Competition in the Pharmaceutical Sector and its benefits for Consumers

**Seventh United Nations Conference to review the UN Set on  
Competition Policy**

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# Need and realisation of competition in pharmaceutical sector

- Pharma an important source of health care for billions of people globally
- Industry is characterized by a more complex structure of decision making and payment
- Influenced by host of unethical practices relate to pricing, patents, quality, safety, marketing & promotions, etc.
- Highly regulated sector – need to have coherence between regulation, competition, consumer welfare and economic efficiency
- Competition is the essence of any market and pharmaceutical sector is no exception

# access TO MEDICINE Index

- It may surprise you but according to Access to Medicine Index 2014 report that ranks pharma companies every two years - *18 of the top 20 global pharma companies have been fined for unethical or corrupt practices in the last few years*



# Recent Anticompetitive Cases in India

- Indian competition watchdog, The Competition Commission of India (CCI) fined global drug makers GlaxoSmithKline (GSK) and Sanofi INR 640 million.
- Both companies formed a cartel to get government tenders
- Eyebrows have also been raised over health ministry for changing the criteria for bidding to supply the particular vaccine.

# Pharma Company Doctor Nexus

## Prescribe and swipe, Doc. All prepaid

G.S.MUDUR

New Delhi, Dec. 22: Many doctors across India have been offered prepaid cash cards as gifts by drug industry representatives over the past three years to try and influence prescriptions for patients, pharmaceutical sales executives have said.

While drug companies have long used largesse as “brand reminders” for doctors, a prepaid cash card leaked by an industry whistleblower appears to be the first evidence to suggest doctors are also being offered cash cards that can be preloaded with up to Rs 50,000.

Pharma sales representatives and bank officials have said several drug companies have procured hundreds of thousands of such prepaid cards over the past three years.

The cards are not illegal

but these transactions occurred at a time two regulatory arms of the government — the Medical Council of India and the Central Board of Direct Taxes — have been trying to discourage drug companies from offering gifts to doctors.

The MCI in December 2009 had notified a code of ethics that prohibits doctors from accepting gifts, travel assistance or hospitality for any purpose amid concerns that such practices could influence doctors to prescribe inappropriate or unnecessary medications.

In August 2012, the CBDT declared that doctors who accept gifts from drug firms should declare the equivalent value as taxable business income while companies should reveal such expenditure on doctors in their annual accounts.

“The practice continues, but it has gone underground,” said Alok Ganguly, vice-president with the Federation of

the Medical Representatives Associations of India, Calcutta. “It has become harder to detect unless insiders reveal things.”

Unethical marketing practices have evoked concern in India and other countries where international drug companies have been under investigation over charges of bribing doctors. Earlier this week, GlaxoSmithKline said it would no longer pay doctors to promote its products.

While **The Telegraph** was collating responses to the Glaxo announcement, a drug industry insider shared with the newspaper an image of a prepaid gift card purportedly issued by HDFC Bank to a Mumbai-based drug company. The card mentions the company’s name, Macleods, and a drug it produces. The validity of the card had expired in March this year. (See visual)

Contacted by this newspa-

per last week, Rajesh Kabu, president at Macleods, neither denied nor confirmed whether his company had issued such prepaid cards to doctors. He said he would need to “check” but did not respond to subsequent telephone queries.

A marketing manager at Macleods and two senior officials outside its marketing department, who requested anonymity, declined to discuss the cards.

Other sources said that if the company had shown the money spent on the cards in its annual accounts, it could not be accused of any illegality, although the ethical propriety of the doctors who might have accepted them could be questioned.

Banking sector officials said Macleods had procured the cards from HDFC Bank between 2010 and 2012 and that the company had since “taken its business to ICICI Bank”.

A sales executive with Macleods, who requested anonymity, has claimed that dozens of doctors across several towns have been offered prepaid ICICI Bank cards this year.

“Some doctors accept them, and some don’t,” the executive said. “They are preloaded with a range of amounts — at times Rs 2,000, at times Rs 5,000 or Rs 10,000.” A bank official said a typical prepaid card could be loaded with any amount up to Rs 50,000.

Bank officials have said both HDFC Bank and ICICI Bank are “fully compliant” with the law, specifically with banking rules that specify that a bank should know its customer. In this case, the customer was Macleods.

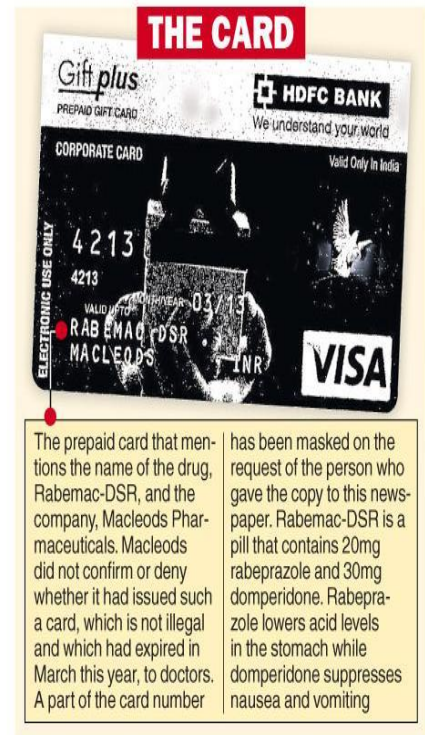
But a prepaid card may be passed on, along with a secret operating pin number, to any end-user. “In such a situation, banks have no idea who the

end-users might be and for what purpose they’re receiving the cards,” an official said.

Pharma executives and bank officials have independently named three other pharmaceutical companies as having procured prepaid cards but have not backed their claims with documents.

Doctors and industry representatives say unethical marketing has survived in the absence of any law that bans such practices. The MCI notification is a code of ethics, while the CBDT expects doctors and companies to comply with its regulations.

“Gifts from drug companies to doctors represent a breach of the code of ethics relevant to professionals such as doctors, although it is legal,” said Sanjiv Lewin, a paediatrician at the St John’s Medical College, Bangalore. “And patients will have to bear the costs.”




# Pharma Company Doctor Nexus

- Such nexus widely discussed and published in Indian media but not much documented evidence
- However, numerous surveys and interviews indicated collusion is quite common in the pharmaceutical market

# Coercive practices in the supply chain

- Instances of shortage of essential medicines on retail shelves after new DPCO was announced in early 2013
- Many wholesalers and distributors found that their margins were eroded and stopped distributing some of these drugs
- Such practices prevent consumer access to affordable medicines

<b>COUNTERING CRUNCH</b>		
<b>Drugs</b>	<b>Formulation/ brands</b>	<b>Duration of unavailability</b>
Oxytocin inj	Syntocinon	July, Aug & Sept
Methyl-ergometrine inj	Methergin	July, Aug & Sept
Metoprolol tab	Cardibeta XR 12.5	Aug & Sept
Metformin 500mg	Riomet OD 500mg	Aug & Sept
Atorvastatin 5, 10, 20	Storvas tablets	Aug & Sept
Albendazole	Bandy tablets	Aug & Sept
Clopidogrel 75mg tab	Plavix	Aug (rationing in Sept)
Paracetamol	T 98 tablets	Aug & Sept
Amikacin inj		Aug & Sept
Diclofenac 50mg tab		July, Aug & Sept

Source: Times of India, 24 September, 2013

# CUTS Interventions in India

- 1995 survey in six states of India
  - 26 percent prescription without mandatory diagnosis
  - About 60 percent of prescriptions were irrational
  - Polypharmacy was found to be very high
- 2010 survey in the states of Assam and Chhattisgarh
  - Only 20 percent consumers obtained medicines from public hospitals as doctors prescribe expensive medicines available only in private chemist shops
  - Incidence of polypharmacy and irrational combination is around 50 percent in both the states

***Common denominator: 'incentives' to mis-prescribe***



# And the consequences are...



# Cases in other jurisdiction

- GSK was accused in China of spending 3bn Yuan (\$490mn) in bribing doctors, hospitals and government officers.
- The French Competition Authority (FCA) in 2013 imposed a fine of € 15.3 million on pharmaceutical company Schering-Plough for defaming a generic drug that competes with its brand name drug and for granting unjustified price cuts to pharmacies
- Past five years: \$13bn paid as fine by leading firms including GSK, Pfizer, AstraZeneca, Merck, Abbot, Eli Lilly and Allergan to settle charges of misleading marketing and bribing doctors

# “Pay for delay” Agreements



- Pay for delay: When drug companies agree not to compete
- A new way of protecting profits for big pharma
- One of the top priorities of FTC and EC in recent years
- According to a FTC study, these anticompetitive deals cost consumers and taxpayers \$3.5 billion in higher drug costs every year
- The European Commission has fined Johnson & Johnson €10.8 million and Novartis €5.5 million for an agreement that involved delaying the market entry of a generic painkiller
- Various other firms such as Lundbeck, Les Laboratoires have been fined for such agreements by FTC and EC

# Unhealthy pricing – is that an antitrust issue?

- High prices of oncology drugs - A huge concern worldwide
- Newer cancer therapeutics cost more than \$100,000 per course of treatment
- Soaring drug prices are unsettling for patients and their families, healthcare providers and insurance companies
- NHS UK recently denied ovarian cancer patients innovative drugs amid cost concerns – NHS UK reject to pay for olaparib (AstraZeneca) on the grounds of cost (GBP 49,000 a year)
- Earlier NHS criticised Roche for refusing to lower the prices of breast cancer drug Kadcyla (GBP 90,000 a year) which is above their approved limit

- Only financially sound patients (like Angelina Jolie) have a reach to such drugs - she has BRCA1 genes which makes highly susceptible to ovarian cancer



- Drug companies tacitly admit that they are taking advantage of highly inflexible consumer demand and raising prices citing R&D costs of innovative drugs
- World over innovative cancer drug prices made them inaccessible to common people



- Product hopping – Another emerging concern to block generic competition
- It occurs when an originator firm launches minor product reformulations that offer little or no therapeutic benefit, but effectively block generic competition

# Way Forward

- Competition advocacy should be strengthened to address information asymmetry
- More use of IP measures such as compulsory licensing
- Prices of patented drugs should be regulated by national government
- Use of competition principles in drug procurement
- Introduction of Competition Impact Assessment tool (CIA) in pharma sector

# Concluding remarks!



***The pharma sector is too clever to allow fair competition, they thrive on sickness and unfair practices!***



**THANK YOU**