National Conference on
Pharmaceutical Policies in India:
Balancing Industrial and Public Health Interests

Conference Agenda
March 06–07, 2014
Venue: **ISID Auditorium, ISID Complex**

Media Coverage

BW|BUSINESSWORLD

55 Top Pharma Brands Not Under Price Control

One of the key recommendations of the study is to review the National List of Essential Medicines

Joe C. Mathew

If you thought that Indian medicine market is highly competitive and fragmented due to the presence of about 10,000 competing drug manufacturing firms, you may not be entirely correct.

An independent analysis carried out jointly by Delhi based think-tanks ***Institute for Studies in Industrial Development (ISID) and Public Health Foundation of India (PHFI)*** shows that at product level, very high percentage of market concentration exists in the domestic market.

At the sub-therapeutic group level, of the 1468 categories of medicines, high level of 80 per cent or above market concentration was visible in the case of 1150. The cumulative market value of these products were Rs 30,687 crore (in 2012), the study states.

Of the 471 products tracked by the researchers, 415 exhibited highly concentrated market features, the study points out.

The analysis turns important as the recently introduced drug pricing policy had shifted the price calculation methodology from cost-based pricing to market based pricing. The underlying logic for this change was the market fragmentation (Abbott, the market leader has less than 7 per cent share in domestic market) and the belief that competition will drive pricing pattern. The new findings will be submitted to the Supreme Court, as part of a 10 year long litigation against central government's drug pricing policy.

The researchers found that the coverage of drugs under the DPCO 2013 is limited to only about 17 per cent of the drugs being prescribed and promoted at present in the country. Stating that the price impact of the implementation of DPCO 2013 is marginal for the retail consumers, the study projected the absolute decrease in sales because of price control at about Rs 1,300 crore, approximately 2 per cent of the Rs 75,000 crore worth domestic drug market.

The study also says that of the 100 top selling brands in the Indian market, 55 of the brands fall outside the scope of price control. Of the top 20 acute brands, eight fall outside, and 13 of the top 20 choric brands are outside price control. It notes that the Drug Price Control Order (DPCO) 2013 has failed to bring newly introduced drugs under its scope. "Of the top 20 newly introduced brands in the last 24 months, majority (18) are outside price control. Given that the primary objective of price control is to contain high prices of medicines, the scope of DPCO 2013 will not extend to new market entrants", the study says.

No of top 20 chronic brands that are not covered under price control

Rank	Brand	Company
2	Glycomet	USV
4	Foracort	Cipla
5	Seroflo	Cipla
6	Galvus Met	Novartis
7	Skinlite	Zydus
8	Cardace	Sanofi
9	Telma	Glenmark
10	Betnovate C	GSK
12	Januvia	MSD
13	Janumet	MSD
16	Telma H	Glenmark
17	Budecort	Cipla
18	Aerocort	Cipla

Source: (Rank based on MAT June 2013: Source - AIOCD-AWACS Market Intelligence Report 2013)

Among the 419 formulations for which ceiling prices were fixed by the National Pharmaceutical Pricing Authority (NPPA) under DPCO 2013, 394 or 94 per cent products enjoy a market share of over 25 per cent or greater, they said. "In 280 cases, the share of market leader in the product is even greater than 50 per cent. But the reduction in revenue for a majority of the market leaders would be limited to the extent of 10 per cent".

One of the key recommendations of the study is to review the National List of Essential Medicines (NLEM), the list that forms the basis for selecting drugs for the purpose of price control. "The revision should rectify prominent omissions and misalignment with current standards of providing treatment as well as take into consideration the state essential medicines lists. A list of life saving medicines should be identified in conjunction with the review of the NLEM and should be brought under price control," researchers Sakthivel Selvaraj, Malini Aisola and Aashna Mehta point out.

However, they do not want a literal reading of NLEM as it gives only specific strengths of medicines. "The scope of coverage should be expanded to include all additional dosages, strengths, delivery mechanisms and combinations of medicines under the NLEM. Acknowledging that the NLEM is only a representative list of medicines that are recommended for various therapeutic areas, the mechanism should also include therapeutic equivalents and close substitutes of medicines in the NLEM", the researchers suggest.

It also calls for a reversal from the market based price arrival mechanism to the earlier method of cost-plus price control mechanism.

The changes, if accepted will hurt the interests of the generic pharmaceutical industry in a big way as that would enlarge the span of price controlled medicines. The industry may also find its export revenues hit as there is an increasing tendency among countries to negotiate prices of imported medicines if the prices in the home market are considerably lower than the prices at which it is sold in the export market.

Commenting on the findings of the report, D G Shah, secretary general Indian Pharmaceutical Alliance (IPA) wanted the recommendations of the study to be seen in the context of long term sustainability of the domestic pharmaceutical industry.

- See more at: http://www.businessworld.in/news/business/pharma/55-top-pharma-brands-not-under-price-control/1289708/page-1.html#sthash.KhNPCuoq.dpuf

BMJ Helping doctors make better decisions

Analysts in India call for urgent expansion of essential medicines list

Anita Jain

Public health policy analysts have called for an urgent revision of the Drug (Prices Control) Order 2013 to expand the list of "essential" medicines, whose prices are fixed, beyond the current 348.

An independent evaluation of the policy by the Public Health Foundation of India and the Institute for Studies in Industrial Development found that this price regulation was limited to 17% of the drugs prescribed in India. This left most of the market untouched and provided only marginal financial relief to patients, the authors said.

The report was released at a conference on pharmaceutical policies in India, held in New Delhi from 3 to 7 March. The authors recommended increasing the scope and coverage of the price control order, as well as abandoning the current market based formula for drug pricing in favour of a cost based formula.

The current policy restricts drug pricing control to formulations that are included in the National List of Essential Medicines (NLEM).

Anurag Bhargava, of the Himalayan Institute of Medical Sciences, told the conference, "This is a matter of concern given that the NLEM was not drafted as an instrument for price regulation. It is a representative rather than a comprehensive list of medicines utilised in actual practice. To serve as a reference for rational prescribing, the NLEM includes only a …Pls Click link to read more…

http://www.bmj.com/content/348/bmj.g2050

Business Standard

Poor access to medicines due to unreliable supply: Report

IANS | New Delhi March 06, 2014 Last Updated at 23:40 IST

Inadequate financing, inefficient procurement and unreliable supply are responsible for poor access to medicines in India, said a new report released Thursday.

The current spending on medicines both by the central and the state governments are a meagre 0.1 percent of the Gross Domestic Product (GDP).

This needs to be scaled up to at least 0.5 percent of the GDP in the next five years, said the report by the Public Health Foundation of India (PHFI) and The Institute for Studies in Industrial Development (ISID).

In addition, the central and state government procurement and distribution systems must be made more efficient and reliable, it said.

They should be modelled on the Tamil Nadu Medical Services Corporation's centralised procurement and decentralized distribution system, the report said.

The direct price control on medicines has given way to liberalisation of the pharmaceutical sector, leading to a scenario where over 82 percent of the medicine market has been left outside the scope of price control under the National Pharmaceutical policy, 2012 and the Drugs (Price Control) Order, 2013.

"Clearly the interests of the pharmaceutical industry have received precedence over the interest of the patient population," the report said.

It goes on to say that the need of the hour is to increase the scope and coverage of price control, and since the current market-based formula is not expected to reduce the prices of medicines significantly, it is strongly recommended that cost-based formula be reinstated.

Yet another but continuing issue is to do away with irrational use of medicines in India.

Not only are hazardous and inessential medicines produced and sold in India but irrational prescription, dispensing and use of medicines is rampant, it said.

Several banned drugs continue to thrive in the Indian market, the report said, adding that evidence suggests that both domestic and foreign pharmaceutical companies in India are not making any significant contribution towards the development of new medicines.

"Policymakers should consider providing direct support for research and development with a clear focus on public health priorities of the country," it said.

See more: http://www.business-standard.com/article/news-ians/poor-access-to-medicines-due-to-unreliable-supply-report-114030601284_1.html

The Telegraph
calcutta, india

Cheap medicine myth busted

G.S. MUDUR

New Delhi, March 6: The rules for price caps on 348 medicines imposed by the central government last year provide drug companies "escape routes" and promise little relief to consumers, a report released today has warned.

The report from the Public Health Foundation of India (PHFI), an academic institution, has also cautioned that the Drug Price Control Order (DPCO) rules will encourage the growth of irrational combinations of drugs that remain outside price control.

PHFI researchers had in November last year presented preliminary results of their study at a conference, indicating that the DPCO covers drugs that account for only 17 per cent of the annual domestic sales worth Rs 72,000 crore.

The new report, described as a comprehensive analysis of the DPCO, has estimated that absolute decrease in the money spent on drugs in India is less than 2 per cent of baseline sales before the price caps came into effect.

"The price control rules do not seem to be the result of genuine intentions to provide relief to consumers," said Malini Aisola, a research associate and health policy analyst at the PHFI, and one of the authors of the report.

The PHFI analysis has found that 18 of the top 20 new drug formulations — ranging from anti-diabetes and anti-cancer medications to vitamins — introduced by pharmaceutical companies in India over the past two years are outside price control.

The top-selling new brand, based on 2013 data from the pharmaceuticals industry, was a fixed dose combination of sitagliptin and metformin, used to treat diabetes, but outside price control. Examples of other drugs outside price control are those used to treat cancers, formulations containing vitamin D and calcium, a drug used to treat skin warts and drugs against HIV.

"We expect this trend to only grow — companies are likely to migrate to formulations not covered by the DPCO," Aisola said. "The meagre 2 per cent relief that consumers seem to be getting now could shrink even more."

A network of health activists called the All India Drug Action Network has challenged the DPCO in the Supreme Court, contending that price caps should be imposed by taking into account the actual production costs of drugs instead of market prices as the DPCO does.

Sections of the pharmaceutical industry and government officials favouring the current form of the DPCO had said in the past that a shift to price caps based on actual production costs would hurt the pharmaceutical industry.

The PHFI report has also cautioned that the DPCO "paradoxically" punishes drug companies that have priced their products below price caps by forcing them to freeze their prices.

"This seems designed to kill the small and medium pharma industry," said Aisola. "These rules punish those who charge less than the ceiling prices. Small companies often don't have deep pockets and could be badly hurt by increases in raw material prices or currency fluctuations."

"There is nothing surprising," said Chandra Gulhati, editor of the Monthly Index of Medical Specialities, India. "But I don't think the report's release has been timed well," said Gulhati. "Who in the government is going to listen to this at this point of time?'

See more: http://www.telegraphindia.com/1140307/jsp/frontpage/story_18054877.jsp#.Ux154_mSz_E

India's first ever national conference on pharmaceutical policies by PHFI and ISID

Editorial Team March 6, 2014 at 5:10 pm

The Public Health Foundation of India (PHFI) and The Institute for Studies in Industrial Development (ISID) are hosting the first ever conference on **'Pharmaceutical Policies in India: Balancing Industrial and Public Health Interests.'** It is a 2 day conference which starts today- March 06, 2014 in New Delhi. The conference will host 32 invited presentations delivered by experts from various fields including policy-makers, academics, and industry leaders. Few of the keynote speakers at the conference include Shri Srikant Jena, Union Minister of State, Chemicals & Fertilizers and Statistics & Programme Implementation, Dr. Arun Panda, Joint Secretary, Ministry of Health and Family Welfare and Dr K Srinath Reddy, President Public Health Foundation of India.

The conference is aimed at discussing various issues on healthcare and related policies in India. The striking highlights of this unique conference include the release two crucial reports by the PHFI: the first of its kind 'Access to Medicines' and the report on 'Drug Price Ceilings.' The 'Access to Medicines' report highlights the present Indian scenario with respect to access to medicines. It will propose feasible policy options to deal with the problem of access to medicines all over the country. The report on 'Drug Price Ceilings' evaluates the drug price order recently implemented by the government, which has a direct impact on the availability of drugs to common man.

The Indian EXPRESS

Drug pricing policy favours market leaders: PHFI report

SUMMARY

The report will be submitted to the Supreme Court where PHFI is one of the petitioners in a case challenging the current NPPP.

In a scathing evaluation of the National Pharmaceutical Pricing Policy (NPPP) 2012, Public Health Foundation of India (PHFI) has concluded, in its report, that the policy is heavily loaded in favour of drug firms, particularly those selling drugs priced on the higher side.

The report 'Pharmaceutical Policies in India: Balancing Industrial and Public Health Interests', recommends that, in patients' interest, the cost-based pricing mechanism should be reverted to, something that experts who compiled the report hold, would mean a decrease of 100-5,000 per cent in prices of the 348 drugs listed in the National List of Essential Medicines.

The report will be submitted to the Supreme Court where PHFI is one of the petitioners in a case challenging the current NPPP.

"By not being logically related to the cost of production, the Drug Price Control Order (DPCO) 2013 obfuscates real costs and by default legitimizes higher prices. Paradoxically, it also punishes manufacturers who had priced their products lower than the ceiling price by freezing it at the same levels. Many of them will be rendered unviable as raw material prices increase, for instance with the falling rupee," the report notes, voicing concerns of health activists who have maintained from the time the policy was notified that it could result in big drug companies monopolising the pharmaceuticals market.

This is not the first time that a report has highlighted irregularities in the drug pricing mechanism. A suo motu study on drug pricing by the ministry of corporate affairs, before the current pricing policy came into effect, had revealed exorbitant profit margins on 21 common drugs manufactured by Indian companies.

Though pricing regulations of the NPPA say that companies can keep a profit margin of maximum 100 per cent over the cost of production (COP) of a drug, mark-ups of 200-500 per cent were found to be very common, with the highest profit margin being 1,122 per cent . Even price-controlled drugs are sold at such exorbitant profit margins, the survey found.

The PHFI report also points out that, in effect, the DPCO takes care of a miniscule 17 per cent of the drug market and also permits the presence of many unsafe medicines in the market.

Dr Shakthivel Selvaraj, one of the authors of the report, says, "There is a lot of discrepancy in the data used to calculate market-based pricing too. While the government assumes there is a 16 per cent margin for retailers, our studies show it can be anywhere between 20-100 per cent. This is why the highest selling brand of a medicine is often also its market leader."

http://indianexpress.com/article/business/market/drug-pricing-policy-favours-market-leaders-phfi-report/

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http://www.deccanherald.com/content/387820/039mncs-lobbyists-campaign-against-indian.html

'MNCs and lobbyists campaign against Indian drugs industry'

Feb 23, 2014 :

A Fulbright scholar and a post-doctoral fellow at Harvard School of Public Health, Shaktivel Selvaraj is an adjunct assistant professor at the Public Health Foundation of India. He was a Health Economist at the National Commission on Macroeconomics and Health in 2004-05. Engaged in teaching and research at PFHI, Selvaraj spoke to Deccan Herald's Kalyan Ray on sub-standard medicine. Excerpts:

How serious is the problem of sub-standard medicine in India?

The term substandard is a catch-all phrase that captures any deviation from regulatory requirements. But not all sub-standard or spurious drugs pose a threat to life. From a public health perspective, only the drugs of 'nonstandard quality' pose the major threat. According to a 2009, CDSCO study, the extent of spurious drugs in retail outlets was only 0.046 per cent and the percentage of drugs failing chemical analysis was only 0.1 per cent (3 out of 2976 samples). In addition, sub-standard drugs accounted for 6-7 per cent of overall tested drugs (state drugs controller estimates). The problem of spurious drugs is nowhere as dire as has been claimed by unverified reports in media.

Is there an underlying Western campaign to malign the Indian pharmaceutical industry, which is a major player in global drugs export market?

There is certainly a campaign by multinational companies and their lobbies to undermine confidence in Indian generics. The chief tactic is to conflate the issue of 'counterfeit' which refers strictly to an intellectual property violation (an egregious trademark violation) with poor quality. The last few years have seen the emergence of an anti-counterfeiting agenda that focuses on misguided global enforcement mechanisms that have nothing to do with real health concerns.

What is the size of the small and medium scale enterprise in the Indian pharmaceutical industry?

The Indian pharmaceutical industry is characterised as 'long-tailed' with approximately 5000 manufacturing units producing drugs, of which only around 250 and large scale units.

Do you think implementation of strict regulatory measures will be an expensive proposition for the SME unit?

Schedule M (good manufacturing practices-GMP) of the Drugs and Cosmetics Act has been implemented since July 2005. Firms were required to come into compliance and during this period several small and medium scale entities were impacted and had to shut down,

particularly those producing bulk drugs. MNCs are engaged in attempts to leverage quality as a barrier to trade.

The main objective should be to aim for appropriate quality and regulatory standards and not only the highest standards.

Why Indian chemist shops don't have qualified pharmacists?

Under current rules, only qualified pharmacists are allowed and provided licences for setting up pharmacies. The lack of enforcement is certainly a challenge.

What are the flaws with the Indian drugs regulatory system? Why the Drugs Controller-General of India could not see these faults which American Food and Drugs Authority discovered with Ranbaxy?

Some of the current challenges facing the regulatory system include inadequate financing, lack of technical workforce and poor infrastructure and capacity for testing of drugs. But inadequate financial resources coupled with poor augmentation of testing laboratories and infrastructure, hiring of skilled personnel has crippled the CDSCO and state authorities' effective functioning. In the case of Ranbaxy, the complaints were related to violations of Standard Operating Procedures and not because of product quality defaults. India has the maximum number of FDA approved plants outside US.

Over 300 plus Indian pharmaceutical manufacturing units have EU mandated GMP certificates, while the largest number of DMFs (Drugs Master Files) approved in US are from Indian Generic firms. A large segment of our drugs manufacturing units are already qualified with Indian GMP.