

Pharma & Healthcare Update

August 12, 2005

IN PIPELINE: NEW DRUG POLICY

By the year end (2005) Indian government is likely to announce a new Drug Policy encompassing Drug Pricing, Funding and Tax policy. The proposed policy is likely to be converted into a statute. This is seen as a significant step in an environment where the Patent Act, 1970 has been changed after 35 years by introduction of a product patent regime.

In the year 2002 an attempt was made by the government to bring in Pharmaceutical Policy 2002 - which, inter alia, dealt with price of essential drugs. However, shortly after it was announced it was challenged in the Karnataka High Court and the Supreme Court and till date has not been implemented.

SOME OF THE SALIENT MEASURES RECOMMENDED IN THE NEW POLICY ARE:

PRICE CONTROL:

In the wake of introduction of the product patent regime in India, price control of essential drugs has gained importance.

The government is planning to amend the existing Drug Pricing Control Order, 1995 ("DPCO") in view of the recommendations by the Sandhu Committee and special task force for drug pricing. DPCO is issued under the Essential Commodities Act, 1955.

The Task Force was created by the Prime Minister of India to arrive at a consensus with the Pharma industry to ensure low-cost drugs for the Indian masses without stifling the global dreams of companies and the Sandhu Committee, was constituted to compile a list of drugs that would be brought under price control.

Sandhu committee's suggestions would deal with price control issues, trade margins and bulk purchases. It has recommended that whenever a new drug is patented its price should be negotiated to keep it at a reasonable level. There has been some debate in respect of definition of the term "life saving". The special task force is likely to recommend on debranding of generics as mentioned by the official from chemicals and petrochemicals ministry.

The policy also proposes to strengthen, the National Pharmaceutical Pricing Authority ("NPPA"), the monitoring of executive body of the DPCO. NPPA is an organization of the Government of India, which was established, inter alia, to fix or revise the prices of controlled bulk drugs and formulations and to enforce prices and availability of the medicines in the country, under the DPCO. The organization is also entrusted with the task of recovering amounts overcharged by manufacturers for the controlled drugs from the consumers. It also monitors the prices of decontrolled drugs in order to keep them at reasonable levels.

ESTABLISHMENT OF FUNDS:

The government is contemplating to set up a fund to disburse loans to small companies which likely to be affected by recent implementation of the Good Manufacturing Practices to upgrade and modernize their plants.

GOVERNMENT WEBSITE:

This website would be listing the prices of generic equivalent drugs giving opportunity to consumer to buy the drugs at the cheapest price. This move will increase the public awareness and promote debranding.

ILLNESS ASSISTANCE:

Under this program the below poverty line (BPL) families will be insured for free treatment.

RESEARCH AND DEVELOPMENT:

To boost the Research and Development ("R&D") activities, it proposed to have a tax rebate of 200 per cent for an extended period of 10 years considering the massive R&D expenditure pharma companies would incur in new patent regime era.

- **Gowree Gokhale & Milind Antani**

Source: Business Standard August 12, 2005

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