VISION IAS

www.visionias.in

(Major Issues for G.S. Advance Batch : 2015)

Drug Pricing in India

Table of Content

1 Background – Need for rational Drug Pricing

- **India's disease burden is higher than world average** and even more than poorer countries like Nepal and Bangladesh. With its large population and high disease burden, the availability of medicines at affordable prices becomes a necessity. In light of these facts sensible drug pricing becomes an imperative.
- Hence, India has adopted a **dual drug pricing policy,** in which prices of some **essential drugs are fixed** while the **rest are controlled by the market** forces of demand and supply, though, government can intervene to regulate the prices of other drugs as well in case of special circumstances.
- Contrary to the common perception, **only 18% of the drug market is under price control** by government and the rest of the drugs are available at the prevailing market prices.

2 Institutional Structure-National Pharmaceutical Pricing Authority (NPPA)

NPPA is under **Department of Chemical and petrochemical**, under **Ministry of chemicals, fertilizers and pharmaceutical**. It was established in 1997 to fix prices of controlled bulk drugs and formulations and to enforce prices and availability of the medicines in the country, under **Drugs (Prices Control) Order, 1995**.

It performs the following functions:

- To implement and enforce the provisions of the Drugs (Prices Control) Order in accordance with the powers delegated to it.
- To monitor the availability of drugs, identify shortages, if any, and to take remedial steps
- To collect/ maintain data on production, exports and imports, market share of individual companies, profitability of companies etc, for bulk drugs and formulations
- To render advice to the Central Government on changes/ revisions in the drug policy.
- To render assistance to the Central Government in the parliamentary matters relating to the drug pricing.

3 How are Drug Prices decided

An **expert committee** appointed by the government prepared the **National list of essential medicines (NLEM)** based on regional epidemiology (patterns, causes, and effects of health and disease conditions in defined populations), cost effectiveness, safety and efficacy.

Government passed **Drug Price Control Order (DPCO), 2013** that included 348 drugs/652 formulations in NLEM based on the recommendations of the committee, replacing the 1995 order that regulated prices of only 74 bulk drugs.

What it meant? –

- Any brand of drugs included in NLEM cannot cost more than the weighted average of all brands (that have a market share of at least 1%) of that particular medicine. This pricing activity is done by NPPA.
- NPPA also issues guidelines for pharmaceutical companies at various times. NPPA recently said that if any medicine is priced lower than the ceiling fixed by the regulator, then companies selling such drugs should maintain the existing or lower retail price.
- It also keeps a tab on all other drug prices as well. It allows a 10% annual hike on other drugs, beyond which companies are required to seek its permission.

4 Recent Controversy- Pricing row involving NPPA

- NPPA on July 10, 2014, released **a new set of price notifications for 108 medicines** for cardiovascular, diabetes TB, cancer and HIV/AIDS under paragraph 19 of the Drug Prices Control Order (DPCO), 2013.
- The Paragraph 19 of the DPCO, 2013, authorized the NPPA to control the prices drugs that are **not under the NLEM under extraordinary circumstances in public interest**. This drew the ire of domestic and multinational manufacturers who went to court against the order, claiming it an overreach.
- Finally, in September, 2014 government revoked Para 19 from DPCO. Thus, NPPA automatically lost power to control prices of the 108 drugs not in NLEM. However, government has allowed pharmaceutical companies to hike rates of 509 essential medicines used for treating various ailments like diabetes, hepatitis and cancer by 3.84 per cent with effect from April 1. It is to adjust the annual increase in the wholesale price index (WPI) that works out to 3.84 per cent and is within the provisions of DPCO.

These events have given rise to a debate on the rationality of drug pricing by the government.

5 Debate about Drug Pricing

Arguments **in favor** of control of drug pricing by the government:

- High disease burden and abundant poverty with low insurance penetration
- It is a necessity if India has to achieve universal healthcare access at affordable costs.
- Medicine is one of those products which are believed to have one of the highest profit margins.
- Artificial inflation of prices by the pharmaceutical companies through use of patent rights, ever greening etc. There exist huge inter-brand differences in branded generics / off patent drugs with similar drug formulation.
- Limited drugs under price control as pharmaceutical companies use various formulations by mixing drugs to avoid being inducted into NLEM.
- The loss estimates presented by industry are exaggerated. High sales of controlled drugs compensate for the lower prices.
- The method used by NPPA still keeps the prices high which can be further reduced using cost based price control mechanism with minimal impact on profits.
- Government allows companies to increase prices of NLEM medicines as per the inflation rate and hence, their profits are not affected.

Arguments **against** the price control:

- There is enough generic competition, and so there is no need to bring down the price of everything.
- People have the choice, and if they do not wish to pay a higher price for a branded drug, they can opt for the cheaper, generic version.
- Price control does not make drugs accessible to the poor or needy but only benefits those who can already afford them. Enforcing price control may actually end up affecting the availability of these drugs in the long term.
- Government funding of drugs in Tamil Nadu and Kerala is a successful models to supply free drugs in government hospitals. They procure drugs outside NLEM also and cover almost 40% of population.
- The highly competitive scenario too does not allow companies to reduce drug prices below certain levels and continue to maintain scale and profits and invest in Research and Development.
- Even after the price control order was expanded two years ago, the sales volume of price-controlled medicines had a compounded annual growth rate of 5% compared with 8% for the same drugs prior to being added to the list in 2013. So it had negatively impacted the sales of such drugs.
- Price controls implemented in China, Philippines and South Korea has had limited impact on improving access. China in fact is planning to replace control prices with market driven prices this year.

6 Role in Universal Healthcare

- In the light of the ongoing debate the role of price control is contested. It is true that **Tamil Nadu and Kerala** models have been successful in increasing healthcare access, but they may not be only model.
- There has been an increase in the healthcare access but, the contribution of drug price control is still not clear. Successful examples of other developing countries like **Brazil** in providing universal healthcare should be carefully studied.
- The **Jan Aushadhi Scheme** providing NLEM drugs and other drugs is an important step towards universalization of healthcare. However, its poor implementation and failure to attract pharmaceutical companies has led to its limited success and hence needs comprehensive revamp.
- Thus, it would be better if an independent expert committee with representation of states industry, hospitals, health practitioners, and civil society is appointed to do a detailed analysis and research and make suggestions on a suitable model regarding price control and distribution of medicines.

7 International Dimension

- Pharmaceutical MNCs are critical of India for unfavorable patent rule and pricing policy of drugs. Hence, foreign firms are apprehensive about their investments and research and development in India.
- In matter of exports, **India is already facing generic drugs export ban by EU** which is costing India about one billion dollars.
- It is also under **US Priority watch list** over its unfavorable IPR regime which affects the India's export capacity there.
- Drug pricing policy has been accused of reducing the profit margins of Indian companies and hence reducing their export competitiveness while reducing their capacity to invest in R & D.

Hence, this dimension also needs to be addressed.

8 Way Forward

India needs to balance the healthcare need of its underprivileged population and the economic impact of such steps on the other side. A cautious and measured approach is needed on the part of policy makers to arrive at a sustainable solution that is well balanced and caters to both our economic and social needs.