

Critical illness drugs remain unaffordable

Steps To Cap Prices Of Life-Saving Meds Prove Futile, Limited Competition Keeps Rates High

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Mumbai: Market dynamics and limited competition in biosimilars (approved versions of complex biologic drugs) and other life-saving drugs have resulted in little reduction in prices, making them unaffordable for many. Surprisingly, government measures to bring down their prices (through the Drug Price Control Orders, or DPCOs) too have been futile, making them out of reach for patients as treatments often run into lakhs of rupees. Biosimilars are used in cancer therapy, rheumatoid arthritis and other critical illnesses.

Even in the case of medicines for hepatitis B and C like sofosbuvir, tenofovir and entecavir, which were brought under price control, there has been little change in the access scenario. The National Pharmaceutical Pricing Authority (NPPA) ceiling price for breast cancer drug trastuzumab is Rs 55,812 (440 mg), marginally lower than that charged by companies at around Rs 58,000, while the ceiling price of another cancer drug rituximab (500 mg) is Rs 36,947, close to the MRP of Ristova (innovator Roche's brand) at Rs 37,500.

Ceiling prices are fixed by NPPA based on a simple average of price to retailer (MRP) of products of companies with over 1% market share. "Given this methodology, wherever the innovator has had an almost monopoly position, the price reduction before and after price control has not been significant. Therefore, given the same methodology being in force, a ceiling price revision after two years can be expected to bring about a further reduction consequent to more players participating in the market and offering products at competitive prices," K V Subrama-

niam, president and CEO, Reliance Life Sciences, said.

Leena Menghaney, treatment activist and lawyer, said, "The system devised by NPPA of fixing prices encourages companies to artificially keep prices high, and hence, works against patients and consumer interests. The government has allowed both multinational and generic countries to profiteer out of the disease of people, driving millions of patients to death."

Andrew Hill from Liverpool University has calculated the treatment costs for a patient. "The drug entecavir is very cheap, and could be made for only \$36 per year, or 10 cents per day. Sofosbuvir can be made for \$1 per day, including a profit margin. So the ceiling price fixed by the government seems high," Dr Hill told TOI.

"The cost of biosimilars needs to be viewed in the context of global prices of these expensive biologics which are be-

OUT OF REACH

PRICE TRENDS OF ONCOLOGY BIOSIMILARS UNDER DPCO

| PRODUCT | BRAND & STRENGTH | CO | BEFORE DPCO* (₹) | AFTER DPCO* (₹) |
|-------------|------------------|----------|------------------|-----------------|
| RITUXIMAB | Ristova 500mg | Roche | 37,500 | 36,947 |
| | Ristova 100mg | Roche | 7,500 | 7,389 |
| | Reditux 500mg | DRL | 39,996 | 36,947 |
| | Reditux 100mg | DRL | 9,999 | 7,389 |
| TRASTUZUMAB | Herclon 440mg | Roche | 75,000 | 55,812 |
| | Canmab 440mg | Biocon | 57,500 | 55,812 |
| | TrastuRel 440mg | Reliance | 60,000 | 58,602 |

PRICES OF ONCOLOGY BIOSIMILARS IN COMPETITIVE MKT

| PRODUCT | BRAND & STRENGTH | CO | PRICE (₹) |
|-------------|------------------|----------|-----------|
| BEVACIZUMAB | Avastin 100mg | Roche | 29,423 |
| | Avastin 400mg | Roche | 1,07,065 |
| | BevacRel 100mg | Reliance | 28,360 |
| | BevacRel 400mg | Reliance | 1,05,010 |

*Drug Price Control Order

The cost of production should be taken into consideration, where medicines included in the National List of Essential Medicines (NLEM) are linked to price control. This is because there is evidence that cost of producing certain off-patent registered drugs is cheap, based on cost of active pharmaceutical ingredient (raw material). "The market is not 100% perfect and, at times, anomalies creep in. In certain cases, there are limitations in making drugs affordable," an NPPA official said.

In the case of hepatitis medicines, pharmacologist

ing provided in India at a fraction of their original cost. The cost of developing a biosimilar ranges between \$50-150 million in comparison to a generic which costs around \$3-5 million. The scale-up of manufacturing is extremely difficult and expensive," Kiran Mazumdar Shaw, CMD, Biocon, said.

However, there is a section which feels that price control alone cannot improve access. "Competitive pricing, local production and compulsory licensing will drive down prices", says Indian Pharmaceutical Alliance secretary general D G Shah.

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