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EXPERT VIEW

KALYANI MENON-SEN | Campaign for Affordable Trastuzumab

MAKING CANCER DRUGS AFFORDABLE

The announcement by Indian biotech company **Biocon** Ltd in November 2013 of marketing approval for a biosimilar of the breast cancer drug trastuzumab was a morale booster for women with HER2+ breast cancer across the developing world.

Hailed as a breakthrough in cancer treatment, trastuzumab reduces the risk of recurrence and gives women with HER2+ breast cancer a better chance of a disease-free life.

The drug, marketed by Swiss pharma company **Roche Holding AG** under the brand name **Herceptin**, is priced exorbitantly the world over. Roche first marketed the drug in India in 2010 at around ₹1.15 lakh per 440mg vial. Soon after the first-ever compulsory licence was issued by the Patent Controller in March 2012. A renamed version (**Herclon**), was then introduced at a lower price—₹72,000 per vial, affordable only to a minuscule percentage of Indian women.

An Indian patent for trastuzumab was granted to **Genentech Inc.** (a Roche subsidiary) in 2007. Although the patent was weak, it prevented other manufacturers from investing in the development of a biosimilar version of the drug.

The Campaign for Affordable Trastuzumab was launched in November 2012 and endorsed by more than 200 patient groups, cancer survivors, eminent jurists, health activists and women's movement groups. The campaign is pressing for government intervention to enable the domestic production of biosimilars and ensure that the drug is made affordable to those who can benefit from it.

In the face of mounting public pressure, and a recommendation by the health ministry for compulsory licensing of trastuzumab, Roche announced in August 2013 that it was relinquishing its patent on trastuzumab. Marketing approval for Biocon's trastuzumab (developed for the US company **Mylan Inc.**) came just three months later.

Despite assurances from Biocon that the biosimilar (**CANMab**) would be made available at an "affordable price", the prices that were announced are ₹19,500 for a 150mg vial and over ₹50,000 for a 440mg vial.

The fact that CANMab will be available in 150mg vials will make life easier for patients on smaller doses. However, there is practically no price advantage. Roche dealers already offer discounts to steady customers—patients needing long-term treatment—such that the "street price" of trastuzumab (**Herclon**) ranges from ₹53,000 to ₹57,000 for a vial of 440mg.

Realistically, only women with a family income above ₹75,000 a month can afford a monthly dose of CANMab. Such families constitute less than 10% of the population. For the majority of Indian women, therefore, Biocon's CANMab is as much out of reach as Roche's **Herceptin** and **Herclon**.

In a new twist, Roche has gone to court and obtained an interim order to block marketing of the biosimilar in India, claiming that Biocon has violated the prescribed procedure. In effect, Roche is claiming a proprietary right over the very word "trastuzumab".

Roche's action bears out the apprehensions of activists that the biosimilar guidelines (formulated by a committee of which Roche was a member) are weighed in favour of Big Pharma.

An estimated 25,000 new cases of HER2+ breast cancer are diagnosed every year in India. The human cost is staggering, whether calculated in terms of loss of lives, the suffering of women or the pain and trauma of their families. In such a situation, the reluctance of the government to act decisively to regulate and control prices of biosimilars like trastuzumab is inexplicable and disturbing.

Other countries are not shy of taking punitive action. The Italian government has just imposed huge fines on Roche and **Novartis AG** for colluding to carve up the market and protect their monopolies by discrediting research showing that **Avastin** (a Roche cancer drug) is an effective treatment for age-related macular degeneration, and can substitute for **Novartis's Lucentis**, which is ten times more expensive.

Roche and Novartis colluded to create an artificial distinction between the two drugs, misrepresenting **Avastin** as "dangerous" if used for anything other than cancer treatment. Roche collected massive royalties from Novartis for the commercialization of **Lucentis**, a deal that has cost the Italian health system €45 million in 2012 alone and has left thousands of elderly Italians at risk of blindness.

It has been encouraging to see the government talking tough—however belatedly—in response to pressure from the US to "tighten" the patent system and ensure that it doesn't serve the interests of Big Pharma. Is this just a show of muscle flexing in an election year, or will it translate into real action?

Kalyani Menon-Sen is campaign coordinator for the Campaign for Affordable Trastuzumab.



Miscellaneous