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Industry body expresses concern over Nexavar decision

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The Association of Biotechnology Led Enterprises (ABLE), a national forum that represents the $4 billion biotechnology industry in India, reacted sharply to India's grant of a compulsory license to Hyderabad-based NATCO Pharma for Sorafenib Tosylate (Nexavar by Bayer), which is used for treatment of liver and kidney cancer.

A statement issued by ABLE says compulsory licenses should be used only when there is a national health crises or when life-saving drugs are priced out of the reach of a common man, that is, under some exceptional circumstances. (Read a comment on the Nexavar license debate)

It further noted that governments are likely to interfere under such circumstances like when a few countries have invoked this provision for making available life-saving HIV drugs to its people. India should always keep in mind that a compulsory license should not be invoked in an arbitrary manner as it will undermine the innovative efforts of this industry and consequently investment in this sector, it says.

Quick factsÃ?Â

NATCO can sell a generic version of Nexavar at a price not exceeding $180 for a pack of 120 tablets (one month's therapy)
Nexavar by Bayer is sold at $5,714 for a month's treatment
The license is valid till the expiry of the patent in 2021
NATCO must meet certain conditions such as maintaining account of sales and payment of royalty at six percent of the net sales on a quarterly basis to Bayer
NATCO is also obligated to supply the drug free-of-cost to at least 600 needy and deserving patients per year

Most multinational and Indian pharma companies spend millions of dollars and many man hours to save patients from life threatening diseases and, therefore, the intent of all these companies broadly is to alleviate suffering of the people, says the statement. However several times, overseas companies price their drug based on who they think can purchase and do not take into account the millions who could be deprived of a treatment due to affordability.

ABLE pointed out that Nexavar is an orphan drug in the US and was not approved by National Institute for Health and Clinical Excellence (NICE) for National Health Service (NHS) use in view of the fact that it increased survival in primary liver cancer by only six months. While on pricing, it is obvious that there is a case on the overall utility of this drug, which prolongs life by half a year, the question is why should India invoke compulsory licensing in the case of Nexavar.

Raising concerns, the statement by the biotech industry forum says, "This is a question that will come up for considerable debate as to whether it is really a true life-saving classification. In future before such rulings are invoked, it might be a good idea to debate on the cost of goods versus the cost of innovation. If we put in mechanisms to compensate the companies which do innovation, then the severity of such rulings will be quite considerably mitigated."

ABLE expressed its concerns by pointing out that the momentum and global image of India's focus on innovation might be at risk, at a time when the Indian government has declared this as the Decade of Innovation.