

DCGI rejects GSK's reply on cervical cancer ad, slaps another notice

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The Drug Controller General of India (DCGI) has rejected GlaxoSmithKline (GSK)'s reply to the show-cause notice issued by the DCGI on GSK in December last year for launching advertisements on cervical cancer vaccine without prior approval from the DCGI.

According to sources, the DCGI has found the GSK's reply in this regard unsatisfactory and has issued another notice to the GSK, asking the multinational drug major to further clarify the reply. In its reply to the DCGI's show cause notice, the GSK is learnt to have pleaded that the advertisements were launched in the country in public interest to instill awareness on cervical cancer which is on the rise in the country.

Sources said that the GSK's reply was not convincing to the DCGI office as there is a feeling that any advertisement to instil public awareness is generally launched by independent bodies or public interest groups who have no commercial interest. But in the GSK's case, that is not true as the GSK has commercial interest in the ad campaign which is clear from the fact that GSK is the one company among the only two companies which have launched cervical cancer vaccine in the country. The GSK had some time back launched the controversial cervical cancer vaccine Cervarix in India.

As the advertisements became controversial, the GSK gave an assurance to the DCGI and unilaterally withdrew the ads. But, the DCGI issued a show cause notice to the GSK in December last year, asking it to explain within 10 days the reasons for such an ad in the media. In the show cause notice, the DCGI had said that the GSK has violated Rule 106, Schedule J of the Drugs and Cosmetics Act, 1940 under which the drug company cannot advertise any drugs. For launching the advertisements, the companies need to take prior permission from the DCGI and in the GSK's case, no such permission was given by the DCGI. Besides, for this kind of ads, the government has to issue a special notification.

Sources also said that if the GSK once again fails to convince the DCGI about the reasons for launching the ads in the national media in the country, the DCGI may contemplate actions against the company. The actions include withdrawal of licenses issued to the GSK's cervical cancer vaccine Cervarix.

During November-December last year, the GSK had launched a no-holds-barred advertisements in several prominent newspapers on the pretext of creating public awareness on cervical cancer. After creating a fear-psychosis among the parents of young girls about dangers of cervical cancer, the full-page ads advocated that vaccination can now prevent cervical cancer long before it happens. GSK had some time back launched the controversial cervical cancer vaccine, Cervarix in the Indian market.