FDA Warns Cancellation of Firms' License to Operate

The Food and Drug Administration (FDA) recently penalized French Pharmaceutical giant Sanofi Pasteur Inc. and drug and beauty chain Watsons Personal Care Philippines for illegally promoting and advertising the dengue vaccine, Dengvaxia.

The FDA said this is a violation of RA 9711 or the Food and Drug Act of 2009 and Administrative Order No. 65.

Section 2.3 of AO 65 provides that "No pharmaceutical product classified by BFAD as prescription or ethical drug shall be advertised or promoted in any form of mass media except through medical journal, publications and/or literature solely intended for medical and allied professions."

Dengvaxia manufactured by Sanofi is classified as a prescription product.

In a Decision dated October 19, both companies were slapped by FDA with a fine of P5,000.00.

Furthermore, Sanofi and Watsons were given a stern warning by FDA that future violations of FDA-implemented laws, rules and regulations shall warrant stiffer sanctions, including the revocation of their License to Operate/Certificate of Product Registration, and the closure of their establishments.

FDA Director General Nela Charade Puno warned Sanofi and Watsons that FDA will not hesitate to cancel their License to Operate and Dengvaxia's Certificate of Product Registration if the companies continue to violate the law.

In 2016, the FDA's Center for Drug Regulation and Research has monitored the airing of the advertising materials on dengue vaccination. It has also reported the unauthorized promotion of the dengue vaccine in the malls.

Puno emphasized that the FDA is serious in enforcing its mandate to ensure that the public is provided only with the correct information on the food, drugs, cosmetics and health devices that they use.

"We are warning local and multinational companies that no one is exempt from the law and they should all comply, or risk having their LTOs and the Certificate of Product Registrations of their medicine products cancelled and revoked."

Sanofi Pasteur Inc., is an affiliate of Sanofi Pasteur, SA, a global pharmaceutical company engaged in the manufacturing, production and distribution of medicines including vaccines.

Puno further directed the FDA's CDRR to defer any future application of Sanofi and Watsons LTO and the CPR of Dengvaxia until and unless the administrative fine imposed by FDA is paid.

She also instructed the FDA’s South Luzon Cluster to check Sanofi and Watsons' compliance with other FDA-implemented laws, rules and regulations.

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