



FDA ADVISORY
No. 2022-2045

29 DEC 2022

TO : PRESCRIPTION PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES (PPPMD) COMPANIES, AND HEALTHCARE PROFESSIONALS (HCP)

SUBJECT : Reiteration Against Unethical Business Practices Related to the Promotion of Prescription Pharmaceutical Products and Medical Devices

In the interest of service, and to ensure that medical decisions are made in the best interest of patients, the Food and Drug Administration (FDA) warns all Prescription Pharmaceutical Products and Medical Devices (PPPMD) companies, and healthcare professionals (HCPs) not to engage in unethical business practices. Specifically, the provisions of Administrative Order (AO) No. 2015-0053 entitled "Implementing Guidelines on the Promotion and Marketing of Prescription Pharmaceutical Products and Medical Devices", on the interactions between PPPMD companies and HCPs, promotional information and activities, entertainment and recreation, and items and gifts, among others shall be observed. It shall be upheld by all stakeholders with the end goal of improving and promoting the rational use of prescription pharmaceutical products and medical devices and safeguarding patient rights and welfare.

The following provisions of A.O. No. 2015-0053 are hereby reiterated:

Section V.B.1. Interactions with Health Care Professionals (HCP)

- a. Industry-HCP relationships shall be based on ethics and transparency to assure the independence of HCP's medical decisions and focus on protecting patients' welfare.
- b. Relationships between company personnel and HCPs shall encourage the development of a healthcare practice committed to patients' well-being based on truthful, accurate, and updated scientific evidence.
- c. PPPMD companies have the ethical obligation to ensure that their interactions with HCPs are in accordance with all applicable laws and regulations.

Section V.B.2. Promotional Information and Activities

- e. No PPPMD company shall employ or contract any HCP or health worker to promote, advertise or endorse any pharmaceutical products or medical device in mass media, print, audiovisual display, or social media.
- g. All advertising, promotional, or other marketing materials, whether written, audio or visual, for products within the scope of this Order, may be subjected to a post-audit by the FDA and if any should be found to violate any FDA provisions, a cease-and-desist order and/or penalties and/or fines shall be issued by the FDA.
- i. Grants, scholarships, subsidies, support, consulting contracts, educational or practice-related items should not be provided or offered to an HCP in exchange for recommending and prescribing medicines, or otherwise in a manner that would interfere with the ethics and the independence of a health care professional's respective practices.

Section V.B.6. Entertainment and Recreation



- a. To ensure appropriate focus on education and informational exchange and to avoid the appearance of impropriety, PPPMD companies shall not provide any form of entertainment that would incur expenses for recreational items, such as tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips, to any healthcare professional.
- b. Entertainment or recreational benefits shall not be offered, regardless of (1) the value of the items; (2) whether the company engages the healthcare professional as a speaker or consultant, or (3) whether the entertainment or recreation is secondary to an educational purpose.
- c. No stand-alone entertainment or other leisure or social activities shall be provided or paid for by companies during scientific meetings.
- d. PPPMD companies are prohibited from paying any travel sponsorship, meals, or other expenses of accompanying guests or family members of HCPs.

Section V.B.7. Educational Items and Gifts

- a. Any item which does not have any direct patient benefit or is not related to the work of the HCP shall not be permitted.
- b. Gifts or personal services and benefits unrelated to the work of the HCP shall not be provided by any PPPMD company representative to a healthcare professional or members of the families.

Section VI. Roles and Responsibilities

3. Industry Associations and Companies shall develop and implement their own standards/codes of ethics for health product promotion aligned with the principles and guidelines of the Order.
4. Healthcare Professionals and Patient Organizations are enjoined to respect, abide and align their own Codes of Ethics to be consistent with this Order.

It is strongly reiterated that unethical business practices related to the promotion of prescription health products and medical devices are subject to sanctions stipulated in A.O. No. 2015-0053.

To report violations related to the promotion and advertisement of prescription drug products and medical devices, kindly email the FDA at **report@fda.gov.ph** or eReport at **www.fda.gov.ph/ereport**. You may also call the Center for Drug Regulation and Research (CDRR) at telephone number (02) 8809-5596 or the Center for Device Regulation Radiation Health and Research (CDRRHR) at (02) 8857-1900 loc. 8301.

For information and guidance.


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Director General 