Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

JUN 08 2021

ADMINISTRATIVE ORDER
No. 2021-0036

SUBJECT: **Guidelines on Compliance with Section 35 (b) of Republic Act No. 11223 (Universal Health Care Act): All Drug, Medical Device, Biological and Medical Supplies Manufacturers to Submit Reports on Disclosure of Financial Relationships with Health Care Providers and Health Care Professionals**

I. BACKGROUND

The 1987 Philippine Constitution declares that it is the policy of the State to protect and promote the right to health of the people and instill health consciousness among them. Consistent with the national health policy, the President of the Philippines signed into law, on 20 February 2019, Republic Act No. 11223 (RA 11223), otherwise known as the Universal Health Care Act (UHC Act), which was passed by the 17th Congress of the Philippines.

Under Item b of Section 35 on Ethics in Public Health Policy and Practice, the UHC Act mandates that "all manufacturers of drugs, medical devices, biological and medical supplies registered by the Food and Drug Administration (FDA) shall collect and track all financial relationships with health care professionals and health care providers and report these to the Department of Health (DOH)." On 10 October 2019, the Secretary of Health signed the Implementing Rules and Regulation (IRR) of the RA 11223, which included the IRR for Section 35(b).

Ethical interactions between drug establishments and health care providers and professionals help ensure that decisions are made in the best interest of the patients. Declaration of financial relationships between manufacturers of health products and health care providers and professionals has public health importance and value. Clinical evaluation and approval of innovative health products, including formulation of regulatory policies, are more efficient when conflicts of interest are addressed and managed through transparency and disclosures. It will redound to more affordable and better access to basic and essential health care services, especially to marginalized sectors of the population.

This issuance hinges on Administrative Order No. 2015-0053 on the Implementing Guidelines on the Promotion and Marketing of Prescription Pharmaceutical Products and Medical Devices. The 21 December 2015 DOH Administrative Order was based on the Asia-Pacific Economic Cooperation (APEC) Principles for Voluntary Codes of Business Ethics contained in the two documents, namely The Mexico City Principles for biopharmaceuticals and The Kuala Lumpur Principles for medical devices, to address unethical business practices, especially in the areas of product promotion and marketing.

This Administrative Order is hereby issued to provide guidelines to ensure compliance by the manufacturers, traders, repackers, distributor-importers, and distributor-wholesalers of drugs, medical devices and biological products, including vaccines, and other medical supplies.

II. OBJECTIVE

This Order aims to provide the guidelines on the implementation of Section 35 (b) of the UHC Act and its Implementing Rules and Regulations, consistent with the provisions of Administrative Order NO. 2015-0053, specifically on the requirements and process of submitting written disclosure report to DOH-FDA pertaining to all financial relationships between manufacturers, traders, repackers, distributor-importers, and distributor-wholesalers of FDA-registered drugs, biologicals, medical devices, and other medical supplies and health care providers.

III. SCOPE

This Order shall apply to all FDA-licensed manufacturers, traders, repackers and distributor-importers and distributor-wholesalers of drug, medical device and biological products, including vaccines, and medical supplies registered with the FDA.

IV. DEFINITION OF TERMS

A. **Authorization** refers to a permission embodied in a document granted by the FDA to a natural or juridical person who has submitted application to manufacture, import, export, sell, offer for sale, distribute, transfer, and/or, where appropriate, use, test, promote, advertise, or sponsor health products. The authorization can take the form of a permit, a license, a certificate of registration, of accreditation, of compliance, or of exemption, or any similar document.

B. **Conflict of Interest** (COI) refers to acts or omissions constituting a conflict of interest under existing laws and civil service rules, including international treaties where Philippines is a signatory. It is a situation created when persons or entities in the public and/or private sectors involved in conducting research, making recommendations and decisions have personal, financial or any other interest that may influence decision-making.

C. **Distributor-importer** refers to any FDA-licensed establishment that imports or exports raw materials, active ingredients and/or finished products for its own use or for wholesale distribution to other establishments or outlets. If the distributor/importer/exporter sells to the general public, it shall be considered a retailer.

D. **Distributor-wholesaler** refers to any establishment that procures raw materials, active ingredients and/or finished products form local establishments for local distribution on wholesale basis.

E. **Financial Interest** refers to any monetary interests gained; i.e. equity interests such as stocks, stock options, intellectual property right, among others, consultancy, board or advisory board membership, lecture fees, expert witness income, industry-sponsored

grants including contracted research, patents received or pending, royalties, stock ownership or options, other personal financial interests and financial relationship.

F. **Health Care Provider (HCP)** refer to any of the following: 1) A Health Facility which may be public or private, devoted primarily to the provision of services for health promotion, prevention, diagnosis, treatment, rehabilitation and palliation of individuals suffering from illness, disease, injury, disability, or deformity, or in need of obstetrical or other medical and nursing care; 2) Community-based Health Care Organization which refers to an association of members of the community organized for the purpose of improving the health status of that community; 3) Pharmacy or drug outlet which refers to establishments licensed under RA 9711 (Food and Drug Administration Act of 2009) which sell or offer to sell any health product directly to the general public or entities licensed by appropriate government agencies, and which are involved in compounding and/or dispensing and selling of pharmaceutical products directly to patients or end users as defined under RA 10918 (Philippine Pharmacy Act); 4) Laboratory and Diagnostic Clinic which refers to licensed facilities where tests are done on the human body or on specimens thereof to obtain information about the health status of a patient for the prevention, diagnosis and treatment of diseases. 5) Health Care Professional which refers to the doctor of medicine, nurse, midwife, dentist, or other allied health professional or practitioner duly licensed to practice in the Philippines.

G. **Manufacturer**, in relation to a health product, refer to an establishment engaged in any and all operations involved in the production of health products including preparation, processing, compounding, formulating, filling, packing, repacking, altering, ornamenting, finishing and labeling with the end in view of its storage, sale or distribution: Provided, That the term shall not apply to the compounding and filling of prescriptions in drugstores and hospital pharmacies. A trader shall be categorized as a manufacturer.

H. **Market Authorization Holder (MAH)** refers to the owner of the permission embodied in a document granted by the FDA to a natural or juridical person who has submitted application to implement the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and/or, where appropriate, the use, testing, promotion, advertising, or sponsorship of health products. The authorization can take the form of a permit, a license, a certificate of registration, of accreditation, of compliance, or of exemption, or any similar document. The MAH is responsible and accountable for the safety, efficacy and quality of the health products approved by the FDA to be in the market.

I. **Pharmaceutical manufacturers** refer to establishments engaged in any or all operations involved in the production of pharmaceutical products including the preparation, processing, compounding, formulating, filling, packaging, repackaging, altering, ornamenting, finishing and labeling, preparatory to their storage, sale, or distribution, except the compounding and filling of prescriptions in pharmaceutical outlets (RA 1098, New Pharmacy Law).

J. **Public Health Ethics** refers to the application of relevant ethical principles and values to guide public health decision making. It involves ongoing ethics analysis, deliberation about, and justification for public health action and policy.

K. **Registration** refers to the FDA process of approval of an application to register health products prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable, the use, testing, promotion, advertisement, and/or sponsorship of health products.

L. **Regular Commercial or Trade Transactions** refers to the sales agreement between two parties or more to exchange items of value, usually money or some other remuneration for goods or services. The Sales Invoice, Official Receipt, or Commercial Receipts/Invoices shall serve as the principal proof of a regular commercial or trade transaction. The delivery receipts, order slips, purchase orders, provisional receipts, acknowledgment receipts, collection receipts, credit/debit memo, job orders and other similar documents that form part of the accounting records of the taxpayer and/or issued to their customers evidencing delivery, or agreement to sell or transfer of goods and services shall serve as the supplementary proof.

M. **Toll Manufacturer** refers to FDA-licensed manufacturers that enters into an agreement or contract with an FDA-licensed trader to manufacture FDA-registered health products for sale or offer for sale or use.

N. **Trader** refers to any establishment which is the owner of a registered health product and procures the raw materials and packing components and provides the production monographs, quality control standards and procedures, but subcontract the manufacture of such product to a licensed manufacturer. In addition, a trader may also engage in the distribution and/or marketing of its products. A trader shall be categorized as a manufacturer. Traders of health products require license to operate issued by the FDA.

O. **Transfer of Value** refers to the direct or indirect transfer of benefits or gains, whether in cash, in kind, or otherwise, made, whether for promotional purposes or otherwise, in connection with the development or sale of drugs, medical device, and biological and medical supplies.

V. IMPLEMENTING GUIDELINES

The following guidelines shall be complied by the Industry Sector covered under this A.O.:

A. All manufacturers, traders, repackers, and distributor-importers and distributor-wholesalers of FDA-registered drugs, medical devices, biological and medical supplies shall document, maintain records, submit to the DOH-FDA and make publicly available data and information on all financial relationships directly or indirectly made with health care providers and healthcare professionals, both in the private and public sectors, in accordance with existing laws, implementing rules and regulations, and guidelines.

B. Financial relationships shall cover the following:

1) For health care providers, all sponsorship of events, research and educational grants, payment of services, space rentals or facility fees, and donations for patients, among other health care provider services arrangements;

2) For health care professionals, all donations, educational grants, research funding, sponsorships related to events, travel, and accommodation, registration fees, honoraria, support for continuing professional development (CPD), royalties, current or prospective ownership or investment interest, consultancy/speakership fees, among other health care professional services arrangements; and

3) Payments to drugstores for disease awareness partnership programs, training of drugstore pharmacists conducted by companies or training of drugstore pharmacists conducted by third parties on behalf of companies, or similar nature of financial relationships, shall be disclosed and reported.

C. The Disclosure Report to be submitted shall not include regular commercial or trade transactions between the company and drug or medical device outlets, including hospitals, hospital pharmacies or clinics, among other establishments or organizations. However, the DOH-Public Health Ethics Committee (PHEC) may request for information from them in the course of conducting investigations as appropriate.

D. The manufacturers, traders, repackers, distributor-importers, and distributor-wholesalers shall regularly submit and update their Disclosure Reports through the FDA Online Disclosure Report System that can be accessed online via https://odrs.fda.gov.ph.

1) It shall be the responsibility of all manufacturers, traders, repackers, distributor-importers, and distributor-wholesalers to record, track and check all financial relationships with HCPs by establishing an electronic database, procedures and system on financial relationships.

2) The President, CEO, Chairperson, owner or top management of all establishments covered by this AO shall be responsible for the completeness and accuracy of the submitted Disclosure Reports. The FDA shall provide him/her the account and access to the FDA Online Disclosure Report System, which may be shared or delegated to her/his authorized officer or personnel for full compliance purposes.

3) Semi-annual regular submission of the Disclosure Report through the FDA Online Disclosure Report System shall be on the 15th of July covering the report of the 1st half of the year, and for reports covering the 2nd half of the year the deadline shall be on the 15th of January, except when the working day falls on a holiday. In such case, the submission of the report shall be the working day before the holiday. Submitted reports shall be updated anytime of the year through the FDA Online Disclosure Report System. Please refer to the sample tables below for further clarification on the reporting:

Report Coverage	Deadline for updating in the FDA Online Disclosure Report System
1st half of the current year	Every 15th of July of the current year
2nd half of the current year	Every 15th of January of the succeeding year

Example:

Report Coverage for 2021	Deadline for updating in the FDA Online Disclosure Report System
1st half of 2021	15 July 2021
2nd half of 2021	15 January 2022

E. The DOH-PHEC may request for updates at any time of the year for the purpose of determining potential or actual conflict of interest, especially when assessing, evaluating or monitoring government or DOH projects or programs.

F. The establishment's relevant database and documentations shall be made accessible to DOH-PHEC for inspection and validation purposes.

G. The updated Disclosure Report shall be made available to the public through a request to the Department of Health using the Presidential Communication Operations Office-Freedom of Information (DOH-PCOO-FOI) online platform.

VI. ROLE AND RESPONSIBILITIES

A. **FDA** - as the National Regulatory Authority of health products, the FDA shall perform the following roles and responsibilities in implementing the provisions of UHC Section 35(b):

1) Provide DOH-PHEC the complete list of manufacturers, traders, repackers, distributor-importers and distributor-wholesalers covered by this AO. The concerned FDA Centers shall be responsible for ensuring the completeness and accuracy of the list of manufacturers, traders, repackers, distributor-importers, and distributor-wholesalers.

2) Through the Information and Communications Technology Management Division (ICTMD) shall develop and maintain the FDA Online Disclosure Report System for the establishments covered under this AO. Develop and improve the minimum data or information set of financial relationships and interest for the disclosure report in collaboration with the PHEC and Health Policy Development and Planning Bureau (HPDPB).

3) Participate in all meetings, deliberations and activities of the PHEC as a member of the Secretariat.

4) In collaboration with the Health Policy Development and Planning Bureau, shall:

a. Conduct series of guidelines dissemination forum through relevant organizations/associations on the use of proposed Online Disclosure Report System and Template on the Disclosure Report.

b. Schedule the pilot/mock and the launching of FDA Online Disclosure Report System.

c. Conduct advocacy activities for HCPs through organizations/associations, government and private hospitals.

B. The **PHEC** - as the duly constituted advisory body under Section 35 of the UHC Act and its IRR, and as further provided in Administrative Order No. 2020-0061 entitled "Guidelines on the Public Health Ethics Review and Creation of the DOH Public and Health Ethics Committee", to assess the ethical soundness of public health practice through monitoring and management of conflict of interest declarations and disclosure reports:

1) Keep track of potential financial interests and relationships, report findings on potential and/or actual conflict of interest and recommend to the Secretary of Health. It shall use the information and data submitted through the FDA Online Disclosure Report System, among other verifiable reports received, in the performance of its duties and functions.

2) May call upon any DOH and other national and local government officials, employees or contract of service for the purpose of clarification, investigation, addressing or managing actual or potential conflict of interest.

3) May call upon health care professionals, health care providers, and the manufacturers, traders, repackers, distributor-importers, and distributor-wholesalers of products covered under this Administrative Orders for the purpose of investigating or clarifying actual or potential conflict of interest.

VII. TRANSITORY PROVISION

All establishments covered by this AO shall submit the first Disclosure Report to DOH-PHEC on 15 July 2021 using the FDA Online Disclosure Report System.

VIII. PENALTY CLAUSE

Failure to submit and update the Disclosure Reports on the part of the manufacturers, traders, repackers, distributor-importers and distributor-wholesalers shall constitute violation of the RA 11223 and its IRR. It shall be a basis or ground for the PHEC to investigate, process, and recommend to FDA to conduct inspection of the manufacturers, traders, repackers, distributor-importers, and distributor-wholesalers and check on the financial relationship with HCPs and report the findings. After due process, the FDA may institute penalty based on the provision of RA 9711 or as may be determined by the Secretary of Health in the exercise of powers under RA 11223 and other laws.

IX. REPEALING CLAUSE

All issuances, or parts thereof, pertaining to the disclosure of financial relationships of drug and medical device establishments, including FDA Circular No. 2013-024, entitled, "The Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector, and the FDA Circular No. 2014-007, entitled, "Adoption of the Kuala Lumpur Principles Device Sector Codes of Ethics", which are inconsistent with this Order are hereby repealed.

X. SEPARABILITY CLAUSE

If any part or provision of this Order is rendered invalid by any court of law or competent authority, the remaining parts or provisions not affected shall remain valid and effective.

XI. EFFECTIVITY

This Order shall take effect fifteen (15) days after publication in the Official Gazette ~~and~~ or in a newspaper of general circulation, and submission of (3) certified true copies to the University of the Philippines-Office of the National Administrative Register (UP-ONAR).

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