Republic of the Philippines
Department of Health
**OFFICE OF THE SECRETARY**

**ADMINISTRATIVE ORDER**
No. 2020 -_____

**SUBJECT:** **Guidelines on Compliance with Section 35 (b) of Republic Act No. 11223 (Universal Health Care Act) by 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 February 20, 2019, Republic Act No. 11223 (RA 11223), otherwise known as the Universal Health Care Act (UHC law), which was passed by the 17th Congress of the Philippines. The provisions of the UHC law seeks "to progressively realize universal health care in the country through a systemic approach and clear delineation of roles of key agencies and stakeholders towards better performance in the health system and to ensure that all Filipinos are guaranteed equitable access to quality and affordable health care goods and services, and protected against financial risk."

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

This Administrative Order is hereby issued to provide guidelines to ensure compliance by manufacturers, traders, repackers and distributor-importers of drugs, medical devices and biological products, including vaccines, and medical supplies registered with the FDA in accordance with the provisions to RA 11223 and its IRR.

## II. OBJECTIVE

The aim for the issuance of this Administrative Order is to provide guidelines on the implementation of Section 35 (b) of the UHC law, specifically on the requirements and process of submitting written disclosure report to DOH pertaining to financial relationships with health care professionals and health care providers by all manufacturers, traders, repackers, and distributor-importers of drugs, medical devices, biological and medical supplies registered by the FDA.

## III. SCOPE AND COVERAGE

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

## IV. DEFINITION OF TERMS

1. 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.

2. 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.

3. 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.

4. Drug refers to (1) articles recognized in official pharmacopeias and formularies, including official homeopathic pharmacopeias, or any documentary supplement to any of them, which are recognized and adopted by the FDA; (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; (3) articles (other than food) intended to affect the structure of any function of the body of humans or animals; or (4)articles intended for use as a component of any articles specified in clauses (1), (2), or (3) but do not include devices or their components, parts or accessories.

5. Establishment refers to a sole proprietorship, a partnership, a corporation, an institution, an association, or an organization engaged in the manufacture,

importation, exportation, sale, offer for sale, distribution, donation, transfer, use, testing, promotion, advertising, or sponsorship of health products including the facilities and installations needed for its activities.

6. Financial Interest refers to any monetary interests gained; i.e. salary or other payments for services or equity interests such as stocks, stock options, intellectual property right, among others, from employment, 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.

7. Financial Relationship means an identifiable health care provider's and health care professional's current or previous business or financial interest in or other business or financial linkage to, one or more individuals, organizations or entities covered by this AO. It also includes receiving or accepting any offer, support or contribution with monetary value for the following: a) continuing professional education which refers to any action designed for or performed for the purpose of acquiring, maintaining, or upgrading knowledge, skills, or attitudes to improve the quality of the health care; and b) events which refers to all promotional, scientific, or professional meetings, congresses, conferences, symposia and other similar events, including, but not limited to advisory board meetings, visits to research or manufacturing facilities and planning or investigator meetings for clinical trials and non-intervention studies organized or sponsored by or on behalf of a company. The connection between a health care provider or health care professional and a company of which they are or were a director and/or shareholder; a trust of which they are or were a beneficiary and/or trustee and/or settlor; a partnership of which they are or were a partner; or a bank account number nominated for the individual or entity is included in the definition of a financial relationship.

8. Health Care Professional shall refer to the doctor of medicine, nurse, midwife, dentist, or other h allied health professional or practitioner duly licensed to practice in the Philippines. A Health Care Professional is also a Health Care Provider. (Please see definition of Health Care Provider.).

9. Health Care Provider (HCP) shall mean 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) A Health Care Professional who may be a doctor of medicine, nurse, midwife, dentist, or other allied professional or practitioner duly licensed to practice in the Philippines; 3) 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; 40 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; 5) 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.

10. Manufacturer refers to an FDA-licensed 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. Manufacturers of health products requires license to operate issued by the FDA. A trader shall be categorized as a manufacturer. (Please see definition of a trader).

11. Market Authorization Holder (MAH) refer 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.

12. Medical device means any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material, or other similar or related article intended by the manufacturer to be used alone, or in combination, for human beings for one or more of the specific purpose(s) of: diagnosis, prevention,, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of, or compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; preventing infection; control of conception; disinfection of medical devices; and providing information for medical or diagnostic purposes by means of in-vitro examination of specimens derived from the human body. This device does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means but which may be assisted in its intended function by such means. The ASEAN Medical Device Directives shall be used as the reference to determine if a health product is considered a medical device.

13. Medical supplies shall refer to consumable supplies (also referred to as disposable supplies) used in the practice of medicine, surgery and other health care providers, diagnostic and testing supplies and equipment, durable medical equipment, acute care supplies, surgical supplies, home health care supplies, diabetic supplies, electronic and life-saving equipment, and other similar products that have unique characteristics and features that are sued by health care providers and health care professionals do their jobs.

14. 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).

15. 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 (CDC, 2015).

16. Public Health Ethics Committee refers to the advisory body constituted by the Secretary of Health to ensure compliance with the provision of Section 35 of the UHC Law.

17. 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.

18. Repacker refers to any establishment that repacks or repackage a finished product into smaller quantities in a separate container and/or secondary packaging, including but not limited to relabeling, stickering, and bundling for promo packs with the end view of storage, distribution, or sale of the product.

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

20. Trader refers to any FDA-licensed 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.

## V. GENERAL GUIDELINES

1. The following FDA-licensed establishments shall submit a Declaration of Financial Relationship with the health care providers and health care professionals in the public and private sectors to the DOH:

1.1. Manufacturers of FDA-authorized (e.g. registered or notified) drugs, medical devices, biological and medical supplies;

1.2. Traders of FDA-authorized (e.g. registered or notified) drugs, medical devices, biological and medical supplies;

1.3. Distributor-Importers of FDA-authorized (e.g. registered or notified) drug, medical device and biological products and medical supplies; and

1.4. Repacker of FDA-authorized (e.g. registered or notified) drug, medical device and biological products and medical supplies.

2. The manufacturers, traders, repackers, and distributor-importers shall regularly submit and update their Disclosure Reports using or by logging in the DOH Online Financial Relationship Disclosure Reporting System.

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

2.2. The electronic recording procedures and system shall be interoperable and accessible to DOH-FDA for inspection and validation purposes.

2.3. The Disclosure Reports shall cover and include all health care providers and health care professionals, both in the private and public sectors, that have financial relationships.

2.4. The President, CEO, Chairman, owner or top management of all manufacturers, traders, repackers, and distributor-importers shall be responsible for the completeness and accuracy of the Disclosure Report. He/She shall be given the account and access to the DOH Online Financial Disclosure Reporting System.

2.5. Regular submission and updating of the Disclosure Report through the DOH Online System shall be on the last working day of the month, except when the working day falls on a holiday. In such case, the submission of the monthly report shall be the working day before the holiday. However, it shall be the responsibility of the manufacturers, traders, repackers, and distributor-importers to submit and update the Disclosure Report as soon as possible when deemed important, urgent and ethical.

2.6. The updated Disclosure Report shall be made available to the public by the manufacturers, traders, repackers, and distributor-importers through their website and make it available upon request.

3. It shall be the responsibility of the FDA to submit and update the complete list of manufacturers, traders, repackers, and distributor-importers covered by this Administrative Order to the DOH.

   3.1. The concerned FDA Centers shall be responsible for ensuring the completeness and accuracy of the list of manufacturers, traders, repackers, and distributor-importers, and for regularly updating the list.

   3.2. The FDA Information, Communication and Technology Division (ICTMD) shall link and integrate the complete list and details of the manufacturers, traders, repackers, and distributor-importers with the DOH KMITS.

   3.3. The names of the manufacturers, traders, repackers, and distributor-importers shall be made accessible to the public through the FDA website.

4. It shall be the responsibility of the DOH KMITS to develop the DOH Public Health Ethics Committee (PHEC) Online Disclosure Reporting System with links from the FDA list of manufacturers, traders, repackers, and distributor-importers.

   4.1. The DOH KMITS shall manage and maintain the Online Disclosure Reporting System, including the management of confidentiality of information. It shall require the manufacturers, traders, repackers, and distributor-importers to submit and update their Disclosure Reports using the DOH Online Disclosure Reporting platform.

   4.2. The DOH KMITS shall provide secured access to the Online Disclosure Reporting System for the PHEC and FDA, among others that it deems appropriate.

5. It shall be the responsibility of the DOH Public Health Ethics Committee (PHEC), as the duly constituted advisory body on matters pertaining to the implementation of Section 35 of the UHC law, to view, review, evaluate and report their findings and recommendations pertaining to financial relationships of HCPs with manufacturers, traders, repackers, and distributor-importers of drugs, medical devices, and biological and medical supplies to the Secretary of Health using the information and data in the Online Disclosure Reporting System, among others.

   5.1. The PHEC shall check, keep track, address and manage all Declaration Reports and determine any actual and potential conflict of interest that may affect or impact DOH and other government health-related project, program, activity, commitment or event, among others.

   5.2. The PHEC may call upon any DOH and other government officials (e.g. LGU officials and employees), employees or contract of service for the purpose of clarification, investigation, addressing or managing actual or potential conflict of interest.

5.3. The PHEC may call upon manufacturers, traders, repackers, and distributor-importers of products covered under this Administrative Orders.

5.4. The PHEC shall coordinate and collaborate with KMITS or the FDA to improve the Online Disclosure Reporting System.

## VI. PENALTY CLAUSE

Failure to submit and updated the Disclosure Reports on the part of the manufacturers, traders, repackers, and distributor-importers shall constitute violation of the RA 11223 and its IRR. It shall be a ground for the PHEC to investigate and, after due process, to recommend to FDA to conduct inspection of the manufacturer or trader to 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 determined by the Secretary of Health in the exercise of power under RA 11223 and other laws.

## VII. REPEALING CLAUSE

All issuances whose provisions are inconsistent with this Order are hereby repealed.

## VIII. EFFECTIVITY

This Order shall take effect thirty (30) working days after publication in one newspaper of general circulation, publication in Official Gazette and submission to the UP ONAR.

**FRANCISCO T. DUQUE III, MD, MSc.**
Secretary of Health