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

SEP 06 2017

**DEPARTMENT ORDER**
**No. 2017 - 0332**

**SUBJECT:** **Guidelines on the Disclosure and Management of Conflict of Interest (COI) in Relation to the Use of Pharmaceutical Products and Medical Devices**

## I. BACKGROUND

The 1987 Constitution provides 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 (Article II, Section 15). Republic Act 7394 (Consumer Act of the Philippines) established the standards of conduct for business and industry in order to protect the interest of the consumers and promote their general welfare. RA 3019 (Anti-Graft and Corrupt Practices Act) regulates the functions of public and private officers to repress possible graft or corrupt practices. In addition, RA 6713 and Administrative Order No. 2009-0004 were formulated to regulate the government officials in adherence to the ethical standards of the Civil Service Commission (CSC).

Administrative Order No. 2015-0053, re: Implementing Guidelines on the Promotion and Marketing of Prescription Pharmaceutical Products and Medical Devices, was created to promote rational use of pharmaceutical products and medical devices. This issuance establishes compliance of both the government and pharmaceutical companies to the principles of integrity, transparency, and public accountability to provide effective, safe, and good quality drugs and medical devices.

As such, the disclosure and management of Conflict of Interest (COI) is relevant in the decision-making of the individual in providing quality health care services through pharmaceutical products and medical devices. This Order is hereby promulgated to provide the guidelines on the disclosure and management of COIs by all concerned individuals in relation to provision and use of quality medicines and medical devices for Filipinos.

## II. OBJECTIVE

To provide a clear, specific, and standard process in the declaration and management of COI within the DOH in order to ensure integrity, address potential graft and corruption practices, and raise the level of public confidence and satisfaction, in relation to recommendations and decisions on the use of pharmaceutical products and medical devices.

## III. SCOPE AND COVERAGE

This Order shall cover all officials and employees of the DOH (permanent and job order) and its attached agencies including DOH and specialty hospitals, members of its advisory and decision-making bodies including members of committees (e.g. hospital Therapeutic Committees, Technical Working Groups, Councils, etc.), technical secretariat, experts, consultants, and resource speakers who provide inputs to the DOH in relation to recommendations and decisions on the use of pharmaceutical products and medical devices.

## IV. DEFINITION OF TERMS

A. **Conflict of Interest** – a situation created when persons or entities in the public and/or private sectors involved in making recommendations and decisions have personal, financial, or any other interest in the pharmaceutical and/or medical device industry, such as but not limited to, having existing ownership or investment therein, being an officer or a member of the Board of Directors of a corporation (including its subsidiaries, affiliates and branches), or a partner in a partnership engaged therein, and receiving any contribution from there. This includes receiving or accepting any favor, offer or contribution, in monetary form or otherwise.

B. **Declaration of Conflict of Interest Form** – the standard form that will be used to identify and address actual or potential conflicts.

C. **DOH – Integrity Management Committee (DOH-IMC)** – the committee created within the Department of Health in accordance with the Integrity Management Program (Executive Order No. 176, s. 2015), which is composed of Assistant Secretaries as chairperson and vice-chairperson, heads of the key management offices as members, and officers that form the sub-committees involved in the integrity management process including but not limited to human resource, finance and procurement, internal audit, and civil society.

D. **Financial Interest** – 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.

E. **Full Participation** – the extent of participation where a member will be allowed to actively take part in all activities and decision-making processes.

F. **Intellectual Interest** – personal views or moral conviction on the importance of a particular area or topic that can influence the scientific opinions of other people.

G. **Medical Device** – 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 in the human body by pharmacological, immunological or metabolic means.

H. **Partial Participation** – the extent of participation where a member will be allowed to actively take part in only certain parts of activities and decision-making process subject to the approval of the members who have full participation.

I. **Pharmaceutical Product** – any pharmaceutical or biological product containing active ingredients responsible for its desired effect intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure or function of the body of man or animal.

J. **Relatives by Consanguinity and Affinity** – these refer to the following which shall include the inso, balaes and bilas as defined under RA 6713:

   a. **First Degree** – these include the declarant's father, mother, son, daughter, father-in-law, and mother-in-law.
   b. **Second Degree** – these include the declarant's brother, sister, grandmother, grandfather, grandson and granddaughter, brother-in-law, sister-in-law, grandmother-in-law, grandfather-in-law, granddaughter-in-law, and grandson-in-law.
   c. **Third Degree** – these include the declarant's nephew, niece, uncle, aunt, nephew-in-law, niece-in-law, uncle-in-law, auntie-in-law.
   d. **Fourth Degree** – these include the declarant's first cousin.

K. **Total Exclusion** – a situation where the member will not be allowed in any step of the deliberation and decision-making processes.

## V. GENERAL GUIDELINES

A. The DOH shall ensure the disclosure and management of COIs of all officials and employees of the DOH (permanent and job order) and its attached agencies including DOH and specialty hospitals, as well as members of its advisory and decision-making bodies including members of committees, technical secretariat, experts, consultants, and resource speakers in relation to recommendations and decisions on the use of pharmaceutical products and medical devices.

B. The DOH shall ensure professional integrity and preserve public trust while sustaining the collaboration with government organizations (GOs), non-government organizations (NGOs), civil society organizations (CSOs), pharmaceutical companies, and other stakeholders.

C. The DOH shall assess all potential practices for undue influence and bias, such as receiving gifts, remunerations, "kick backs," bribes, rebates, and other forms of incentives that may be provided by the industry or partners of the official or employee.

D. The DOH shall maintain clear criteria in the appropriate selection and appointment of members of technical and decision-making committees and working groups.

E. The DOH shall enforce proper implementation of the ethical standards and protocols as well as the ethical standards in the promotional marketing and advertisement of pharmaceutical companies.

F. All health professionals shall responsibly disclose COIs to ensure the protection of patients' welfare and maintain integrity in their practice. They shall disclose any circumstance that could result to potential COI related to their functions in which they will be engaged, and comply with the policy on management of such.

G. The Declaration of COI form of the Food and Drug Administration **(Annex A)** shall be adopted and used by all concerned parties covered by this Order. This form must be completed by all officials and employees of the DOH and its attached agencies, members of advisory groups and committees, experts, consultants, resource speakers, board members and alternates, delegation members at board meetings, and non-administrative employees of the secretariat.

H. Failure to submit and update completed forms may result in non-appointment to the body in question.

I. The DOH office in charge of the deliberation or decision-making process shall designate its staff who will serve as the technical secretariat for the said activity. The technical secretariat shall coordinate among the individuals who will declare COIs, and submit the forms to the DOH-IMC, copy furnished the Personnel Division.

J. Situations that may arise which are not covered by these guidelines shall be addressed by the DOH-IMC.

K. This Order shall be evaluated for its effectiveness two (2) years after its effectivity and may be revised when the need arises.

## VI. SPECIFIC GUIDELINES/IMPLEMENTING MECHANISMS

### A. Declaration of Conflict of Interest

1. All officials and employees shall complete the Declaration of COI form where they must disclose any financial, intellectual, or other interests relevant to their function in which they have been asked to participate, as well as any interest that could be affected by the outcome of the their function. Not completing and disclosing all relevant information from this form may, depending on the circumstances, lead the DOH, through the DOH-IMC, to decide not to appoint them to the advisory bodies/functions in the future.

2. They shall also declare relevant interests of their families and relatives within the fourth degree of consanguinity or affinity and other parties with whom they have substantial common interest/s that may be perceived as unduly influencing their judgement.

3. The duly notarized completed Declaration of COI Form shall be submitted to the technical secretariat copy furnished the Personnel Division for inclusion in the 201 File of DOH officials and employees, one (1) week after the invitation to participate in the activity was received, or not later than one (1) month before their participation in the activity. A separate file for consultants or experts shall also be maintained.

4. Copies of accomplished forms shall be submitted by the technical secretariat to the DOH-IMC for evaluation.

5. The persons with COIs shall promptly inform the technical secretariat of any change of information prior to the course of carrying out their function.

**B. Management of Conflict of Interest**

1. The management of COI shall apply to financial, intellectual, and all other interests pertaining to, but not limited to pharmaceutical products and medical devices.

2. The deliberation or decision-making process shall be presided by a Chairperson. In case the Chairperson has a COI, he/she shall appoint the vice-chairperson to preside.

3. The individual without a COI for a particular topic under deliberation shall be allowed full participation in the deliberation or decision-making process.

4. Any individual with COI shall be categorized as either under partial participation or total exclusion.

5. Partial participation shall be enforced on a member whose declared COI includes: membership in the Speaker's Bureau, Consultancy Group or Advisory Board, receipt of gifts, non-research grants, sponsorships, or rewards with total amount not exceeding PhP 15,000 per year per sponsor. This shall also apply to members whose relatives have COIs related to pharmaceutical products and medical devices.

6. Total exclusion shall be enforced on a member whose declared COI includes: any investment interests; regular employment in the commercial entity or organization to which the topic/issue being discussed is related to; authorship in a clinical trial or research involving the topic/issue under deliberation; receipt of monetary or non-monetary support for research valued at more than PhP 50,000 per year; receipt of gifts, non-research grants, sponsorships, or rewards with the total amount exceeding PhP 15,000 per year per sponsor. He/she shall be given this restriction for a period of one (1) year and shall continue until his COI ceases to exist

7. For those reported to have not disclosed COI intentionally:

    a. Total exclusion shall be applied.
    b. An investigation on the veracity of the report shall be conducted by the DOH-IMC and if proven so, he/she will be subjected to administrative sanctions based on existing government rules.
    c. The individual/s shall be restricted to participate for a period of one (1) year, which shall continue until the issue is resolved.

**C. Process of Participation**

1. Each individual or member of the body or committee shall declare any interest relevant to the topic/issue being discussed.

2. The extent of participation of the member shall be determined by the DOH-IMC based on the nature and magnitude of the interest, timeframe and duration of the interest.

3. Full participation shall be allowed for the member without COI.

4. Members with full or partial participation shall proceed with the discussions.

5. Members with full or partial participation shall prepare ground rules for formulation or recommendations.

6. Members with partial participation shall be allowed to present.

7. Only members with full participation shall vote to make the final recommendations with respect to the issue/topic under deliberation.

**D. Roles and Responsibilities**

1. The DOH officials and employees (permanent and job order), DOH attached agencies including DOH and specialty hospitals as well as members of its advisory and decision-making bodies including members of committees, technical secretariat, experts, consultants, and resource speakers shall:

    a. Accomplish the Declaration of COI form completely;
    b. Comply with the Management of COI; and
    c. Ensure that all concerned complies with the Management of COI.

2. The DOH office who shall conduct the deliberation or decision-making process shall provide the technical secretariat who will perform the following:

    a. Provide copies of the Declaration of COI forms;
    b. Collect and keep the accomplished Declaration of COI forms;
    c. Process reports of undisclosed COI; and

d. Submit the forms and reports to the DOH-IMC, copy furnished the Personnel Division.

3. The DOH-IMC shall:

   a. Maintain a database of all advisory bodies and keep record of the Declaration of COI forms;
   b. Verify the truthfulness of information entered in the COI form; and
   c. Conduct investigation for those who refuse to disclose all COI and completely fill up the Declaration of COI forms. The DOH-IMC members shall convene to discuss this matter when necessary. It shall likewise meet and resolve the issue with the person and inform him/her of its decision in writing.

4. The DOH-Personnel Division shall maintain a copy of the Declaration of COI forms and include in the 201 File of the DOH officials and employees.

## VII. PENALTY CLAUSE

The DOH shall impose sanctions pursuant to RA 3019, Sections 9, 11, 12 and 13, as applicable (http://www.lawphil.net/statutes/repacts/ra1960/ra_3019_1960.html).

## VIII. REPEALING CLAUSE

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

## IX. EFFECTIVITY

This Order shall take effect immediately.

**PAULYN JEAN B. ROSELL-UBIAL, MD, MPH, CESO II**
Secretary of Health

**Annex A**

# DECLARATION OF CONFLICT OF INTEREST

**1. CURRENT FINANCIAL INTERESTS**

To your knowledge, do 1) you, your spouse, minor child, general partner, 2) organization in which you serve as an officer, director, trustee, general partner, or employee and/or 3) entity with whom you are negotiating or have any arrangement concerning prospective employment have any current involvement or financial link with the meeting/task issues (including competing companies)?

**a. INVESTMENTS** (e.g. stocks, bonds, retirement plans, trust, partnerships, sector funds, etc.) ☐ **NONE** (If "none," skip to Item b.)

| ESTABLISHMENT | TYPE OF INVESTMENT | OWNER (self, spouse, etc.) | NUMBER OF SHARES | CURRENT VALUE | CHECK PERCENTAGE NET WORTH | | |
|---|---|---|---|---|---|---|---|
| | | | | | LESS THAN 5% | 5-15% | MORE THAN 15% |
| | | | | | | | |
| | | | | | | | |

**b. EMPLOYMENT** (Full or Part Time) (Current or Under Negotiation) ☐ **NONE** (If "none," skip to Item c.)

| ESTABLISHMENT | RELATIONSHIP | POSITION IN FIRM | DATE OF EMPLOYMENT OR NEGOTIATIONS BEGAN |
|---|---|---|---|
| | | | |
| | | | |

**c. CONSULTANT/ADVISOR** (Current or Under Negotiation) ☐ **NONE** (If "none," skip to Item d.)

| ESTABLISHMENT | TOPIC/ISSUE | AMOUNT RECEIVED | DATE FROM | DATE TO | RELATED TO LISTED PRODUCTS/ INDICATIONS/ ISSUES |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |

**d. CONTRACTS/GRANTS** (Current or Under Negotiation) ☐ **NONE** (If "none," skip to Item e.)

| TYPE OF AGREEMENT (contract/grant) | PRODUCT UNDER STUDY AND INDICATIONS | AMOUNT OF REMUNERATION TO | | TIME PERIOD | SPONSOR* | YOUR ROLE** | AWARDEE | RELATED TO LISTED PRODUCTS/ INDICATIONS/ISSUES |
|---|---|---|---|---|---|---|---|---|
| | | INSTITUTION | YOU | | | | | |
| | | | | | | | | ☐ YES ☐ NO |
| | | | | | | | | ☐ YES ☐ NO |
| | | | | | | | | ☐ YES ☐ NO |

* Governmnet, Establishment, Institution, Individual

** Site Investigator, Principal Investigator, Co-Investigator, Employee, Partner, No Involvement, or Other

**IF MORE SPACE IS NEEDED, PLEASE ATTACH ADDITIONAL PAGES**

**1. CURRENT FINANCIAL INTERESTS (Continued)**

**e. INTELLECTUAL PROPERTY** ☐ **NONE** (If "none," skip to Item f.)

| FOR | ESTABLISHMENT | RELATED TO LISTED PRODUCTS/ INDICATIONS/ISSUES | IF "YES," EXPLAIN BELOW AND INDICATE INCOME RECEIVED |
|---|---|---|---|
| | | ☐ YES ☐ NO | |
| | | ☐ YES ☐ NO | |
| | | ☐ YES ☐ NO | |

**f. EXPERT WITNESS** (Last 12 months or under negotiation) ☐ **NONE** (If "none," skip to Item g.)

I appeared for or against the following listed establishment(s) and issue(s)

| FIRM AND ISSUE | AMOUNT RECEIVED | RELATED TO LISTED PRODUCTS/ INDICATIONS/ISSUES | IF "YES," EXPLAIN BELOW |
|---|---|---|---|
| | | ☐ YES ☐ NO | |
| | | ☐ YES ☐ NO | |
| | | ☐ YES ☐ NO | |

**g. SPEAKING/WRITING** (Last 12 Months or under negotiation)

| FIRM | TOPIC/ISSUE | AMOUNT RECEIVED | | DATES | RELATED TO LISTED PRODUCTS/ INDICATIONS/ISSUES |
|---|---|---|---|---|---|
| | | HONORARIUM | TRAVEL | | |
| | | | | | ☐ YES ☐ NO |
| | | | | | ☐ YES ☐ NO |
| | | | | | ☐ YES ☐ NO |

**2. PAST FINANCIAL INTERESTS**

a. To your knowledge, do 1) you, your spouse, minor child, general partner, 2) organization in which you serve as an officer, director, trustee, general partner, or employee have any past involvement with the meeting/task issues:

☐ YES ☐ NO ☐ NOT TO MY KNOWLEDGE

b. If "Yes," describe involvement.

| FIRM/PRODUCT | FINANCIAL INVOLVEMENT (e.g. contract/consultant) | ROLE | DATES | RELATED TO LISTED PRODUCTS/ INDICATIONS/ISSUES |
|---|---|---|---|---|
| | | | | ☐ YES ☐ NO |
| | | | | ☐ YES ☐ NO |
| | | | | ☐ YES ☐ NO |
| | | | | ☐ YES ☐ NO |

**IF MORE SPACE IS NEEDED, PLEASE ATTACH ADDITIONAL PAGES**

**3. OTHER INVOLVEMENTS** (Other Kinds of Relationships) ☐ **NONE** (If "none," skip to Item 4.)

Using the list of products/firms/issues, identify anything that would give an "appearance" of a conflict which has not been disclosed above (e.g. involvement in a lawsuit, researcher initiated study, gift of research materials, etc.)

_____

_____

_____

_____

**CONSENT TO DISCLOSURE**

By completing and signing this form, you consent to the disclosure of any relevant conflicts to other meeting participants and in the resulting report or work product.

**DECLARATION**

I hereby declare on my honour that the disclosed information is true and complete to the best of my knowledge.

Should there be any change to the above information, I will promptly notify the responsible staff of the DOH and complete a new declaration of interests form that decribes the changes. This includes any change that occurs before or during the meeting or work itself and through the period up to the publication of the final results or completion of the activity concerned.

| **DATE** | **SIGNATURE** |
|---|---|
| | |