Notification of the Ministry of Public Health

Re: Ethical Criteria for Drug and Non-Drug Medical Supply Procurement and Promotion of the Ministry of Public Health, B.E. 2564 (2021)

Unethical procurement and promotion of drug and medical supplies and irrational drug use leading to unnecessary consumption of drugs and non-drug medical supplies at exorbitant prices are part of the problems of patient access to essential drugs and Thailand's rising health care expenditures. Unethical promotion has drawn public health personnel into a variety of complex forms of conflict of interest, such as receiving directly and indirectly benefits from drug or non-drug medical supply companies such as pecuniary benefits, gifts, overseas trips, etc. The fact that sales promotion during procurement process and irrational use of drugs and non-drug medical supplies have become normal practices in the Thai society has also led to a misunderstanding among public health personnel that such benefits are within their right without realizing the negative impacts of such practices on government budgets, good governance of the pharmaceutical, system and the overall health system.

The Ministry of Public Health has issued the Notification of the Ministry of Public Health Re: Ethical Criteria for Drug and Non-Drug Medical Supply Procurement and Promotion of the Ministry of Public Health, B.E. 2564 (2021) as an operational guideline for the good governance practices of the government agencies, work and service units under the Ministry of Public Health as well as drug prescribers, public health professionals and personnel involved in the procurement process, use of drugs and non-drug medical supplies.

The National Anti-Corruption Commission of Thailand (NACC) had conducted a study on measures to prevent corruption in the Civil Servant Medical Benefit Scheme (CSMBS) drug reimbursement process on June 2017. The study found that almost all work and service units under the Ministry of Public Health have established guidelines that comply with the Ethical Criteria for Drug and Non-Drug Medical Supply Procurement and Promotion of the Ministry of Public Health, B.E. 2564 (2021). It also found them to strictly observe the Ministry of Finance Regulations on Acceptance of Cash or Property Donation to the State, B.E. 2526 (1983) and the Ministry of Public Health Regulations on Service Fees of the Service Units under the Ministry of Public Health, B.E. 2536 (1993) and its amendments in their handling of donation from drug companies, but there is a lack of documentation system for information on donated properties to hospitals under the Ministry of Public Health. Investigations conducted by the Office of Public Sector Anti-Corruption Commission (PACC) and the Department of Special Investigation found corruption networks among three groups of people: CSMBS users and their relatives, hospital personnel, and drug companies. Moreover, NACC had presented

the Cabinet with facts on three types of drug reimbursement misconducts: assuming another person's rights under false pretense, drug shooting, and drug shopping to be used as guidelines on the prevention and solutions to corruption problems the CSMBS reimbursement process as follows:

1. System-based recommendations

1.1 Advance the Ministry of Public Health's Rational Drug Use (RDU) strategy to encourage medical personnel to base their drug dispensing decision on academic ground rather than on benefits from drug companies.

1.2 Establish a pharmaceutical information processing center with linkage to hospitals of all affiliations and the Comptroller General's Department to verify dishonest reimbursement claims. While such center has not yet been established, the Comptroller General's Department must set up measures to control CSMBS outpatient expenditure.

1.3 Prescribe drug procurement criteria

1.3.1 Procurement units are prohibited from earning revenues from all forms reciprocal benefit as contribution to a hospital's welfare fund.

1.3.2 Procurement units must take the product's costs, standards, time, services, and prices into consideration when making decision.

1.3.3 Procurement units must specify qualifications of their trade partners in a draft Term of Reference. The trade partners must observe the criteria in Article 136 of the Organic Act on Anti-Corruption, B.E. 2561 (2018). There must be an ethical criteria training system for personnel with positive scores for training on price performance.

1.3.4 Procurement units shall adopt the price negotiation mechanism prescribed by the National Pharmaceutical System Development Committee.

1.4 Intensify internal audit system stringency both at the hospital and its responsible agency levels.

2. Mission-based recommendations

2.1 Strict enforcement of the law by relevant work units.

2.2 Advance compliance with the ethical criteria for drug promotion.

2.2.1 The Ministry of Public Health and the National Pharmaceutical System Development Committee shall enforce the ethical criteria in a tangible manner, publicize, foster and raise awareness of the importance of appropriate drug promotion among public health personnel and the public.

2.2.2 The professional councils relating to the provision of public health services shall establish ethical criteria relating to drug promotion and dispensing that are in keeping with the relevant professional ethics.

2.2.3 Employ ethical criteria as a strategy to promote good governance in the procurement system and control the hospital's pharmaceutical expenditure.

2.3 Raise relevant personnel conscience and promote public engagement:

2.3.1 The work units' original affiliation shall publicize and disseminate knowledge on ethical criteria for personnel acknowledgement and declare mutual intention to observe the ethical criteria.

2.3.2 Hospitals shall publicize and disseminate knowledge on the ethical criteria, drug promotion and rational drug use in easy-to-understand media formats, establish a network consisting of hospital personnel and the public. Monitor and scrutinize drug promotion operations and irrational drug use. Establish channels for filing direct complaint and notification of criminal acts to responsible work units.

2.3.3 The Comptroller General Department shall publicize and disseminate knowledge on the exercising of CSMBS rights to entitled persons for correct understanding and practices and avoidance of dishonest use of their rights.

2.4 Establish proper internal audit standards for the private sector to prevent inappropriate drug promotion.

On 12 September 2017, the Cabinet passed a resolution to approve NACC's recommendations and appoint the Ministry of Public Health as the principal agency, in conjunction with other related agencies, for the driving of compliance with the Ethical Criteria for the Procurement and Sales Promotion of Drugs and Non-Drug Medical Supplies of the Ministry of Public Health, B.E. 2557 (2014). The Ministry shall be responsible for its enforcement in order to prevent the aforementioned corruption.

Whereas it is deemed expedient to revise the Ethical Criteria for the Procurement and Sales Promotion of Drugs and Non-Drug Medical Supplies of the Ministry of Public Health for compliance with the Cabinet's resolution and enforcement on the government agencies, work and service units under to the Ministry of Public Health for strict observation in order to prevent any conflict of interest in the procurement and promotion of drugs and non-drug medical supplies, dishonest performance of duties or misconduct against the official position and duties, as well as for the provision of positive role models for other work units.

By virtue of Section 20 of the State Administration Act, B.E. 2534 (1991), as amended by the State Administration Act (No. 5), B.E. 2545 (2002), in conjunction with the intention of Section 128 of the Organic Act on Anti-Corruption, B.E. 2561 (2018), the Minister of Public

Health hereby issues the Ethical Criteria for Drug and Non-Drug Medical Supply Procurement and Promotion of the Ministry of Public Health, B.E. 2564 (2021) as follows:

Clause 1 This Notification is called the "The Notification of the Ministry of Public Health Re: Ethical Criteria for Drug and Non-Drug Medical Supply Procurement and Promotion of the Ministry of Public Health, B.E. 2564 (2021)".

Clause 2 This Notification shall come into force from the day following the date of its publication in the Government Gazette onward.

Clause 3 The Notification of the Ministry of Public Health Re: Ethical Criteria for Drug and Non-Drug Medical Supply Procurement and Promotion of the Ministry of Public Health, B.E. 2557 (2014) shall be repealed.

Clause 4 In this Notification,

"government agency" means a department or government agency of any other name with a departmental status under the Ministry of Public Health;

"work unit" means a work unit at the divisional level or its equivalent under the Ministry of Public Health that performs the tasks of procurement or regulating the use of drugs and non-drug medical supplies;

"service unit" means a service unit under the Ministry of Public Health Regulations on Service Fees of Service Units under the Ministry of Public Health.

"ethical criteria" means the ethical criteria for of drug and non-drug medical supply procurement and promotion of the Ministry of Public Health;

"pharmaceutical system good governance" means a good administration of the pharmaceutical system, ranging from the selection, procurement, distribution, and observation of the ethical criteria in accordance with the state administration good governance principles prescribed by the Office of the Public Sector Development Commission (OPDC), which was approved by the 24 April 2012 Cabinet resolution;

"drug" means a drug under the law on drugs, narcotics under the law on narcotics and psychotropic substances under the law on psychotropic substances;

"non-drug medical supply" means medical materials, dental materials, medical science materials, x-ray materials, other materials used for medical purpose, including medical supplies for use with a specific patient;

"drug and non-drug medical supply promotion" means the information, statements, invitations, incentives or any other conducts provided by sellers with the intention of obtaining a prescription, purchase order or utilization of drugs and non-drug medical supplies for the sellers' commercial benefits;

"advertisement" means an act performed through any methods to cause the public to perceive or acknowledge statements about a drug and non-drug medical supply for commercial benefits;

"statement" means a narrative or fact presented in the form of alphabets, numbers, pictures, films, lights, sounds, marks or any other forms to communicate meanings on their own or through any other methods or media;

"gift" means a benefit in the form of an asset, object or souvenir that a drug or non-drug medical supply company presented to a person for commercial benefits;

"drug and non-drug free sample" means a drug and non-drug free sample distributed to a person, government agency, work unit or service unit to familiarize them with its appearance and characteristic in order to enhance their clinical experiences, except for those distributed for a study or research purpose (in the case where such free samples are provided for procurement consideration);

"other benefits that may be calculated as cash benefits" means a valuable object as well as the benefits of a discount, entertainment, service, training or any other benefits of the same nature or any acts that result in the person having received any benefits that may be calculated as cash benefits or an exemption from any expense, as prescribed by the Notification of the National Anti-Corruption Commission Re: Criteria for the Acceptance of Properties or Other Benefits under the Ethical Criteria of State Officials, B.E. 2563 (2020);

"normal custom" means a festival or an important day on which gifts may be exchanged, including an opportunity for people to offer congratulation, gratitude, welcoming reception, condolence or assistance which are acceptable social manners;

"prescriber" means a government officer who is a medical professional or other type of public health personnel with the rights or duties to prescribe drugs and non-drug medical supplies;

"professional" means a government officer who practices the art of healing, dentistry, pharmacy, nursing, medical technology, physical therapy, Thai traditional medicine, community public health and a professional or practitioner in other branches of the art of healing pursuant to the royal decrees issued under the law on the practice of the art of healing;

"drug company representative" or drug and non-drug medical supply sales representative means a representative of a drug company and a distributor of non-drug medical supplies whose duties are to meet professionals to present information on drugs and non-drug medical supplies;

"drug or non-drug medical supply company" means a company, an ordinary person or a juristic person or an organization relating to the production, import and sale of drugs and non-drug medical supplies both domestically and internationally (including a drug or non-drug medical supply company relating to a foundation, association, organization, etc.) as well as the Government Pharmaceutical Organization;

"administrator" means a government officer who has the power to make a decision, sign or order a selection, purchase, and procurement of drugs and non-drug medical supplies of a hospital or work unit;

"authority" means a group of government officers whose duties are to select, purpose, procure or order a purchase order of drugs and non-drug medical supplies for a work unit or a service unit;

"personnel involved in the procurement process" means a government officer who through his or her position or an assignment is responsible for the procurement of a work unit or service unit;

"student" means a premed student who is studying at an educational institution;

"educational institution" means an educational institution at the college and university level or an institution participating in a joint instruction of a medical or public health program, the Praboromarajchanok Institute, a medical center hospital or a general hospital or an educational institution under the Ministry of Public Health which provides medical personnel instruction. educational institution

Clause 5 Government agencies, work units and service units shall:

(1) formulate guidelines for the practice of this ethical criteria and have them displayed as a written announcement in a conspicuous place within sixty days from the date that this Notification comes into force;

(2) announce mutual intention to observe the guidelines that are in keeping with the present ethical criteria;

(3) apply the present ethical criteria to promote pharmaceutical system good governance, foster and raise awareness of the present ethical criteria among relevant personnel, the understanding of the conflict of personal and public interests, and to advance concrete promotion of the rational drug use strategy.

Clause 6 The Permanent Secretary of the Ministry of Public Health shall have charge and control and has the power to issue rules for the implementation of this Notification. In case of problems with the observation of this Notification, the Permanent Secretary of the Ministry of Public Health shall have the final decision.

CHAPTER 1
Prescribers

Clause 7 Prescribers shall not accept benefits from a drug or non-drug medical supply company in the following manners:

(1) Cash in whichever case, except for academic speaker's remunerations, travel expenses and accommodation expenses, and cash in the form of research fund provided by a drug or non-drug medical supply company;

(2) Gifts, souvenirs, assets or any other benefits that may be calculated as cash benefits which are donated to government officials and their spouses or relatives, with the exception of:

(1.1) any item that they may receive during the course of their performance of duties under the law or regulations or in a reasonable amount under a normal custom or when such item is given to the general public or in accordance with NACC's announcement;

(1.2) anything with academic benefit to the medical and public health services as well as patient benefits can be accepted on behalf of their hospital or work unit.

Clause 8 Prescribers must not commercially present themselves to the public in an advertisement or drug and non-drug medical supply promotion.

Clause 9 Prescribers must not accept support directly from a drug or non-drug medical supply company to attend an academic meeting, conference, training or study visit, both locally and internationally.

Clause 10 Prescribers must disclose their beneficial relationship with a drug or non-drug medical supply company when presenting their academic opinions about such drugs and non-drug medical supplies to the public either verbally or in writing or through any other means.

Clause 11 Prescribers can accept research support the work unit's or service unit's support acceptance and regulation systems.

Clause 12 In giving drug and non-drug medical supply free samples to patients or work units, prescribers must give primary consideration to patient benefits and safety and must not do so for their own personal benefits. Such practice shall be carried out through the regulatory system for the acceptance and dispensing of drug and non-drug medical supply free samples of the government agency, work unit or service unit. The system should be a verifiable system.

Clause 13 When issuing a prescription, prescribers must use the drug common names.

CHAPTER 2
Administrator or the authority

Clause 14 Administrators or the authority must insist that the work units under their supervision shall strictly observe the ethical criteria by establishing guidelines that are in keeping with but not lower in standard than the present ethical criteria and post them as written announcement in conspicuous places for personnel acknowledgement.

Clause 15 Administrators and the authority must formulate policies and establish a good governance system to prevent any conflict of interest for the following activities:

(1) Selection of drug and non-drug medical supply to obtain quality drugs and non-drug medical supplies shall be carried out in accordance with the prescribed standards.

(2) Procurement of drugs and non-drug medical supplies shall be carried out in accordance with the Government Procurement and Supplies Management Act, B.E. 2560 (2017) as well as the Ministerial Regulations and rules issued under the Government Procurement and Supplies Management Act, B.E. 2560 (2017). The ethical criteria for drug distributors can be taken into consideration for the selection of drug or non-drug medical supply companies, which must be purchased at net prices.

(3) Acceptance of financial support from a drug and non-drug medical supply company through a purchase of drugs and non-drug medical supplies must not be used as a means to earn revenues from all forms reciprocal benefits.

(4) Acceptance and prescription of drug and non-drug medical supply free samples must give primary consideration to patient benefit and safety, and must not aim to be the promotion of drugs and non-drug medical supplies or to gain any personal benefits.

(5) Regulation of drug and non-drug medical supply promotional activities in government agencies, work units or service units by, for example, determining the time and place for such activities, establishing criteria for the government agencies', work units' or service units' acceptance of support, and prohibiting the following activities with covert advertising purposes:

(5.1) drug company representatives, drug and non-drug medical supply company's sales representatives are permitted to conduct activities at the agreed time and place;

(5.2) acceptance of personal support from a drug or non-drug medical supply company is prohibited, except when the support is given to a work unit or a service unit and closely regulated for the benefit of the government agency, work unit or service unit;

(5.3) activities aiming to provide health knowledge to the public in association with the trade name of the drugs and non-drug medical supplies or any activities that constitutes a covert advertisement are prohibited;

(5.4) administrators or the authority must set up strict and efficient corruption risk and conflict of interest risk management systems and an internal audit system.

Clause 16 Administrators or the authority must strictly observe the same ethical criteria as those applied to the prescribers in Chapter 1.

CHAPTER 3
Pharmacists or other professionals and personnel involved in the procurement, prescribing and delivery processes of drugs and non-drug medical supplies

Clause 17 Pharmacists or other professionals and personnel involved in the procurement, prescribing and delivery processes of drugs and non-drug medical supplies shall observe the present Ethical Criteria by:

(1) strictly observing the same ethical criteria as those of the prescribers in Chapter 1;

(2) conducting activities in accordance with the prescribed policies and systems to ensure transparency, accountability, and absence of conflict of interest;

(3) preparing and presenting reliable technical information and evidences to supplement decision on the selection of drugs and non-drug medical supplies to the Pharmaceutical and therapeutic Committee (PTC) or a committee of any other name that is responsible for the selection of drugs and non-drug medical supplies for a work unit or service unit without hindering any company in particular or gaining benefits for oneself or another person.

Clause 18 Do not publicize or distribute documents, brochures, signages or any other forms of media containing exaggerated advertisement or promoting drugs and non-drug medical supplies to patients and the public.

CHAPTER 4
Government agencies, work units, service units

Clause 19 Establish guidelines that are in keeping with the present ethical criteria and the contexts of each government agency, work unit and service unit but not lower in standard than the present ethical criteria and post them as written announcement in conspicuous places for personnel acknowledgement.

Clause 20 Implement the policies, establish good governance system and prevent any conflict of interest in the following activities:

(1) Selection of drugs and non-drug medical supplies that are in keeping with the prescribed quality standards.

(2) Procurement of drugs and non-drug medical supplies shall be carried out in accordance with the Government Procurement and Supplies Management Act, B.E. 2560 (2017) as well as the Ministerial Regulations and rules issued under the Government Procurement and Supplies Management Act, B.E. 2560 (2017). The ethical criteria for drug distributors can be taken into consideration for the selection of drug or non-drug medical supply companies, which must be purchased at net prices.

(3) Acceptance of financial support from a drug and non-drug medical supply company through a purchase of drugs and non-drug medical supplies must not be used as a means to earn revenues from all forms reciprocal benefits.

(4) Patient benefit and safety must be the primary consideration when accepting and prescribing drug and non-drug medical supply free samples to patients without aiming for the drug and non-drug medical supply promotion or personal benefits;

(5) Regulation of drug and non-drug medical supply promotional activities in government agencies, work units or service units shall be carried out as follows:

(5.1) drug company representatives, drug and non-drug medical supply sales representatives are permitted to conduct activities at the agreed time and place;

(5.2) acceptance of personal support from a drug or non-drug medical supply company is prohibited, except when the support is given to a work unit or a service unit and closely regulated for the benefit of the government agency, work unit or service unit;

(5.3) activities aiming to provide health knowledge to the public in association with the trade name of the drugs and non-drug medical supplies or any activities that constitutes a covert advertisement are prohibited;

(6) acceptance of support to organize academic conferences in the forms of operating budgets, speaker expenses or academic information provided by a drug and non-drug medical supply company is permitted, but must always be disclosed for participant acknowledgement.

(7) acceptance of support from a drug and non-drug medical supply company to attend a meeting, conference, training, study visit or academic presentation both locally and internationally is permitted only in the following cases:

(7.1) for the organizing of an academic conference or training that is beneficial to the government agency or work unit or service unit with no obligation to promote the company's drugs and non-drug medical supplies;

(7.2) must be done in the name of a government agency, work unit or service unit; there must be a system for support acceptance and criteria for the of suitable personnel to attend a meeting, conference, training, study visit or academic presentation both locally and internationally; only support for travel expenses, registration fees, speaker expenses, food and accommodation expenses for the attendee will be accepted for the duration and site of the study visit, conference or academic presentation.

CHAPTER 5
Educational Institutions

Clause 21 Educational institutions must:

(1) prohibit drug company representatives or drug and non-drug medical supply company sales representatives from meeting with students for the purpose of drug and non-drug medical supply advertisement;

(2) prohibit any activities aiming to provide drug and non-drug medical supply information to students in association with the trade name of the drugs and non-drug medical supplies the name of the drug and non-drug medical supply company to prevent any covert advertisement;

(3) prohibit students from directly accept of cash, gifts, donated items or any form of endorsement from a drug and non-drug medical supply company, except when they are given as unconditional educational support through an educational institution and are publicly disclosed;

(4) establish systems for the acceptance of support and regulation of all forms of educational support and activities from drug and non-drug medical supply companies to ensure transparency and prevent advertisement and promotion of drugs and non-drug medical supplies;

(5) regulate and control its faculty members and personnel to provide positive role models for students, both in terms of the ethical conducts of all levels of personnel and appropriate relationship with drug and non-drug medical supply companies, their representatives or sales representatives;

(6) offer educational programs aiming to educate and foster positive attitudes about rational use of drugs and non-drug medical supplies and access to reliable drug and non-drug medical supply data sources without any business influences.

(7) offer educational programs focusing on the ethical conducts of all levels of personnel and appropriate relationship with drug and non-drug medical supply companies, their representatives or sales representatives

(8) establish a policy that requires its faculty members and personnel to disclose their relationship with a drug and non-drug medical supply company when expressing academic opinions to the public either verbally or in writing or through any other means.

CHAPTER 6
Drug and non-drug medical supply companies and their representatives or sales representatives

Clause 22 Drug and non-drug medical supply companies or their representatives or sales representatives shall observe the Notification of the National Pharmaceutical System Development Committee Re: National Ethical Criteria for Sales Promotion, B.E. 2559 (2016), dated 22 April 2016.

Notified on 9 April 2021.
Anutin Charnvirakul
Minister of Public Health

แบบฟอร์มการขอเผยแพร่ข้อมูลผ่านเว็บไซต์ของหน่วยงานในราชการบริหารส่วนกลาง
สำนักงานปลัดกระทรวงสาธารณสุข
ตามประกาศสำนักงานปลัดกระทรวงสาธารณสุข
เรื่อง แนวทางการเผยแพร่ข้อมูลต่อสาธารณะผ่านเว็บไซต์ของหน่วยงาน พ.ศ. ๒๕๖๑
สำหรับหน่วยงานในราชการบริหารส่วนกลางสำนักงานปลัดกระทรวงสาธารณสุข

แบบฟอร์มการขอเผยแพร่ข้อมูลผ่านเว็บไซต์ของหน่วยงานในสังกัดสำนักงานปลัดกระทรวงสาธารณสุข

ชื่อหน่วยงาน : ศูนย์ปฏิบัติการต่อต้านการทุจริต กระทรวงสาธารณสุข
วัน/เดือน/ปี : ๘ พฤศจิกายน ๒๕๖๕
หัวข้อ: ประกาศกระทรวงสาธารณสุข เรื่อง เกณฑ์จริยธรรมการจัดซื้อจัดหาและการส่งเสริมการขายยาและเวชภัณฑ์ที่มิใช่ยาของกระทรวงสาธารณสุข พ.ศ. ๒๕๖๔ ลงวันที่ ๙ เมษายน พ.ศ. ๒๕๖๔ (ฉบับภาษาอังกฤษ แปลโดยศูนย์การแปลและล่ามเฉลิมพระเกียรติ คณะอักษรศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย)

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Link ภายนอก: ไม่มี

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(นางสาวสุชาฎา วรินทร์เวช)
ตำแหน่ง นักวิเคราะห์นโยบายและแผนชำนาญการพิเศษ
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ผู้รับผิดชอบการนำข้อมูลขึ้นเผยแพร่
พศวีร์ วัชรบุตร
(นายพศวีร์ วัชรบุตร)
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