Code of Practice

NIHON GENERIC Co., Ltd.

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[Introduction]

NIHON GENERIC Co., Ltd. (hereinafter referred to as “the Company”) is required to stably provide high-quality generic drugs at reasonable prices and contribute to the improvement of national health and welfare through healthy development of the pharmaceutical industry.
In order to gain the confidence of society with regard to the proper use of drugs, the Company has further developed the former “Prescription Pharmaceutical Promotion Code” and established and decided in April 2014 to implement a “Code of Practice” (hereinafter referred to as “the Code”) which applies to interactions between all the board members/employees and investigators, healthcare professionals, and patient groups, etc.

The Company must always ensure high morality and transparency in such interactions, achieve accountability for interactions with investigators, healthcare professionals, patient groups, and wholesalers, etc., in order to gain the confidence of society.

I Code of Practice

In light of the fact that the Company is a member of the life-related industry and conducts its corporate activities under the public healthcare insurance system, the Company shall comply with related laws and regulations such as the Pharmaceutical and Medical Device Act, etc., Standards for Adequate Advertisement of Drugs, etc., Guidelines for Sales Information Provision Activities for Ethical Drugs, as well as the Fair Competition Code, Code of Ethical Practice for Pharmaceutical Companies, and other self standards, and shall act with high ethical standards.

1. Scope and Definition of Promotion

1.1 Scope

The Code shall apply not only to promotional activities for prescription pharmaceuticals but also to all interactions between the Company and investigators, healthcare professionals, medical institutions, patient groups, and wholesalers, etc. The Company shall comply with the Code and respect the IFPMA Code. The Company shall also act always taking into account whether the action is taken in accordance with the purpose of the Code regardless of whether the Code specifies it or not.

1.2 Definition of Promotion

"Promotion" does not mean "sales promotion" but means "efforts to provide/collect/communicate medical information for healthcare professionals to promote the proper use of prescription pharmaceuticals and disperse the idea".

2. Responsibilities of Top Management

The top management of the Company shall conduct the following:

(1) Take the initiative to set a good example of compliance with the Code, thoroughly inform related persons of the Code, and establish internal systems based on the idea that Top Management is responsible for the actions of all board members/employees.

(2) Take responsibility to solve issues, investigate causes, and strive to prevent recurrence in the event of non-compliance with the Code.

(3) Have departments not in charge of drugs respect the spirit of the Code and conduct corporate activities.

(4) Have subsidiaries (holding >50% of shares) that manufacture/market drugs in Japan comply with the Code.

(5) Announce the necessity of compliance with the Code to the parent/partner companies and subsidiaries that manufacture/market drugs in and outside Japan to gain their understanding.

3. Basics of Interactions

3.1 Basics of Interactions

Advancement of medical/pharmaceutical sciences and improvements in public health are based on interactions intended to share information in the whole medical service community including investigators, healthcare professionals, patients and wholesalers. Such interactions essentially require integrity (actions with generosity and loyalty). In such interactions, society demands that decisions be made ethically and from the patient's standpoint. The Company shall act to gain trust from the government, healthcare professionals, and patients, etc., that the Company always conducts its activities in an ethical manner.

3.2 Transparency of Interactions

Pharmaceutical companies are required to be highly ethical as life-related companies. The Company is accountable for having ethical and loyal interactions with investigators and healthcare professionals and cooperation with patient groups. The Company shall ensure the transparency of corporate activities and be appropriately accountable for society under the corporate guidelines based on the Guidelines for Transparency of Corporate Activities and Relationship with Medical Institutions (hereinafter referred to as "Medical Institutions Transparency Guidelines") by the Japan Generic Medicines Association.

4. Interactions with Healthcare Professionals

In interactions between the Company and healthcare professionals, contribution to patients' benefits, as well as health and welfare, shall be prioritized. Interactions are intended for the Company to contribute to advancement of medical/pharmaceutical sciences and improvement of public health, with a focus on provision of pharmaceutical information, academic interactions for medical/pharmaceutical sciences, and support for research. The Company shall also build a relationship of trust with investigators, healthcare professionals, and patients, etc., in promoting academic-industrial collaboration for advancement of medical/pharmaceutical sciences and must not conduct any corporate activity likely to inappropriately influence decisions on prescriptions.

5. Prohibition of Information Provision before Approval and Recommendation of Off-label Use

No promotional activities of drugs are allowed before approval in Japan. Off-label uses must not be recommended.

6. Activities for Offering Information

The Company, as a life-related company, shall appropriately provide scientific/objective information on drugs. In providing such information, the Company shall strive to ensure that the contents/expressions are easily understandable for users and comply with legal regulations and self standards.

The Pharmaceutical and Medical Device Act and Standards for Adequate Advertisement

of Drugs, etc., prohibit advertisement of prescription pharmaceuticals for the general public other than healthcare professionals. Therefore, when the Company offers information through press releases or activities to enlighten the general public or patients, or to provide information to investors, the Company shall thoroughly review the contents from the planning stage so that the information is not suspected to be an advertisement for prescription pharmaceuticals or an advertisement to promote off-label use of unapproved drugs. Activities to provide information to healthcare professionals is specified in "II. Prescription Pharmaceutical Promotion Code".

6.1 Promotional Materials (including Electronic Media)

The Company shall prepare promotional materials (including electronic media, hereinafter referred to as "Promotional Materials") in compliance with related laws and regulations as well as self standards such as preparation guidelines, etc.

6.2 Social Media

The Company shall be fully responsible for the contents of digital communication using social media, etc. Therefore, the Company shall confirm such contents beforehand with related subsidiaries, parent and partner companies, planning companies, agents, and employees, etc., in compliance with the Code.

7. Lectures and Meetings

The Company may hold lecture meetings to provide information on medical/pharmaceutical sciences and information for awareness of diseases. In holding lecture meetings, etc., the Company shall make the content appropriate as a pharmaceutical company and comply with the Fair Competition Code and related laws and regulations by selecting appropriate locations and venues.

When the Company invites healthcare professionals to a meeting to seek professional advice on corporate activities, the Company must not use the meeting as a means of sales promotion. The Company shall select appropriate persons in light of the purpose of the meeting, and the number of attendees shall be minimized.

8. Outsourcing

The Company may outsource operations such as research, clinical trials, post-marketing surveillance, consultants, advisors, participation in meetings, chairing or lecturing at meetings, instructors for training, etc., to investigators, healthcare professionals, medical institutions, and patient groups, etc., and pay remuneration and expenses, etc. However, when outsourcing such operations, the Company must conclude a contract, and the contract must satisfy all of the following:

(1) A written contract that specifies the purpose of operations and the rationale for payment such as remuneration and expenses, etc., shall be concluded
(2) Legitimate necessity of the operation shall be clearly identified before the

operation is outsourced

(3) The contractor of the operation shall be directly related to the identified necessity and has the expertise necessary to provide the service

(4) The operations shall be outsourced to an adequate number of persons to achieve the identified necessity

(5) The operation must not induce prescription, purchase, or recommendation of a specific drug

(6) The remuneration for the operation shall be appropriate as compensation for service

9. Provision of Goods/Money

The Company shall not directly/indirectly provide goods or money likely to inappropriately impact the decision-making of stakeholders in the whole medical service community such as investigators, healthcare professionals, medical institutions as well as patient groups and wholesalers.

The Company shall not provide goods that may compromise the integrity of drugs or goods/money that cannot be understood/approved by society even if the above does not apply to such goods/money.

10. Drugs for Trial Use

Drugs for trial use are one of the means to provide medical information and intended to show healthcare professionals the characteristics of drugs or used to support the confirmation/evaluation of the quality, efficacy, and safety, etc. Therefore, when a drug is provided for trial use, it must be provided together with its information and in a minimum amount.

11. Study/Research Activities

The Company is actively committed to contributing to human health, welfare and healthcare, research & development of generic drugs with good quality and reasonable price to increase convenience for patients and healthcare professionals and improvement of formulation technologies. These activities and other study/research activities must be highly ethical and legitimately scientific at each stage in accordance with standards/laws and regulations, and ethical guidelines, etc., stipulated by the government. The research & development expenses and scientific research funding derived from such study/research are subject to public disclosure based on Medical Institutions Transparency Guidelines and laws and regulations. Further, the Company shall be accountable for ensuring the transparency of clinical study information, etc.

The Company shall also further organize research & development systems for appropriate self-control of laboratory animals necessary for development from the viewpoint of animal welfare.

12. Relationship with Patient Groups

The relationship between the Company and patient groups must be highly ethical with respect for independence of patient groups.

With regard to monetary support for patient groups provided by the Company, the involvement of the Company must be clarified in order to gain the understanding that such support contributes to the activities/development of patient groups. The purpose/details of support shall be agreed on in writing and the records shall be documented to ensure transparency. In this regard, when any payment is made to a patient group, the Company shall establish self standards and comply with them.

13. Relationship with Wholesalers

The relationship between the Company and wholesalers must be a fair business relationship in compliance with related laws and regulations such as Anti-Monopoly Act, etc., as well as industrial self standards. In light of the fact that business transactions are made under the public healthcare insurance system, the industry is required to ensure more ethical and transparent relationships than other industries. Therefore, the Company shall establish self standards for providing or receiving monetary payment, goods, food and drink, and comply with those standards.

14. In-house Procedures and Education

The Company shall establish and maintain appropriate in-house procedures to comply with related laws and regulations and the Code, and provide appropriate education to all the board members and employees according to their roles.

15. Overseas Activities

15.1 Standards Applicable to Overseas Activities

The Company shall comply with the Code for activities in overseas countries and also comply with the codes of the pharmaceutical industry in the relevant country if there are such codes, or the IFPMA Code if there are no such codes, in addition to related laws and regulations in the country.

15.2 Provision of Pharmaceutical Information in Overseas Country

With regard to pharmaceutical information to be provided to healthcare professionals outside Japan, the Company shall provide internationally consistent pharmaceutical information directly or through agents in compliance with the codes of the pharmaceutical industry in the relevant country if there are such codes, or the IFPMA Code if there are no such codes in addition to related laws and regulations in the country.

15.3 Actions Taken Outside Japan for Domestic Healthcare Professionals and Actions Taken in Japan for Overseas Healthcare Professionals

The Company shall comply with the Code when inviting Japanese healthcare professionals to overseas lecture meetings and academic conferences. When inviting overseas healthcare professionals to Japanese lecture meetings or academic conferences, the Company shall comply with the codes of the pharmaceutical industry in the relevant country if there are such codes, or the IFPMA Code if there are no such codes, in addition to related laws and regulations in the country.

15.4 Actions Taken by Overseas Subsidiaries, Licensees, and Agents

For activities by overseas subsidiaries in overseas countries, the Company shall have the subsidiary comply with codes of pharmaceutical industry in the relevant country if there are such codes, or the IFPMA Code if there are no such codes, in addition to related laws and regulations in the country. When the Company has overseas licensees or agents involved in activities in the relevant countries based on a license contract or agent agreement, the Company shall request them to comply with codes of pharmaceutical industry in the relevant country if there are such codes or the IFPMA Code if there are no such codes in addition to related laws and regulations in the country.

II Prescription Pharmaceutical Promotion Code

"Prescription Pharmaceutical Promotion Code" (hereinafter referred to as the "Promotion Code") clarifies the code of practice to be complied with by pharmaceutical companies when they conduct promotions of prescription pharmaceuticals, and it is intended for all board members/employees belonging to companies to appropriately conduct promotion activities. "Promotion" is defined not as "sales promotion" but as "efforts to provide/collect/communicate pharmaceutical information for healthcare professionals to promote the proper use of prescription pharmaceuticals and disperse the idea". The Company shall always consider whether the action is in line with the spirit of the Promotion Code irrespective of whether or not the Promotion Code explains specific rules. Further, any promotional act that violates legal regulations, Standards for Adequate Advertisement of Drugs, etc., Guidelines for Sales Information Provision Activities for Ethical Drugs or self standards shall be deemed an act against the Code even if there is no specific description in the Code.
The Promotion Code will be revised in association with establishment or revision/abolition of the IFPMA Code, related laws and regulations and self standards, and in accordance with changes of other regulations and environmental changes related to promotional activities.

1. Company's Responsibilities in Promotional Activities

The Company shall be fully responsible for its own promotional activities including activities by medical representatives (hereinafter referred to as "MRs") and, with this recognition, shall establish in-house systems to conduct appropriate promotion and ensure it covers all board members/employees. The Promotion Code shall apply to promotional activities, as well as activities deemed promotion, regardless of whether the organization that conducts the activities is in charge of sales or not.

(1) Appropriate MRs shall be appointed, and education and training shall be continuously provided for the proper use and dissemination of drugs.
(2) Evaluation/remuneration systems must not induce unethical acts by MRs, etc.
(3) Information on the indications and dosage and administration of drugs shall be provided appropriately within the scope of approval and based on the latest data with clear scientific grounds.
(4) Pharmaceutical information shall be collected and communicated accurately and promptly.
(5) In-house systems to comply with related laws and regulations, as well as self standards, shall be established.

2. Code of Practice for MRs

MRs shall be fully aware of their social mission as people who play a part in medical care and their position to carry out activities involving pharmaceutical information as representatives of a company, and faithfully conduct the following:

(1) Strive to acquire knowledge related to package inserts, as well as medical/pharmaceutical knowledge as the basis of such knowledge, and foster the ability to properly provide it.
(2) Conduct promotion in accordance with the contents and methods specified by the Company.
(3) Provide information on indications and dosage and administration within the scope of approval as a drug in a fair and balanced manner in terms of efficacy and safety.
(4) Collect and communicate pharmaceutical information accurately and promptly.
(5) Must not defame other companies or products.
(6) Comply with regulations stipulated by medical institutions and act in an orderly manner when visiting medical institutions.
(7) Comply with related laws and regulations and act sensibly as an MR.

3. Preparation and Usage of Promotional Materials

The Company shall be aware that promotional printed materials, advertisements in professional journals (paper), websites for healthcare professionals, slides, audiovisual materials including movies and other promotional materials prepared by the Company are important means to provide pharmaceutical information. In preparing and using such materials, the Company shall comply with the Pharmaceutical and Medical Device Act/administrative notifications and related self standards such as preparation guidelines, ensure that the contents of such materials are accurate, objective, and fair based on scientific rationale, and comply with the following (1) to (10):

(1) Descriptions of indications, dosage, and administration are not outside the range of approval.
(2) False or exaggerated displays, layouts, and expressions of efficacy and safety or displays, layouts, and expressions likely to induce misunderstanding must not be used. Expressions must not particularly emphasize/ensure safety.
(3) Contents of such materials shall be well balanced and shall not excessively show information on efficacy but also include safety information such as data on adverse drug reactions, etc.
(4) Comparisons with other agents shall be made based on objective data with the use of the generic name.
(5) Descriptions must not defame other companies and products.
(6) It must not focus only on exceptional data and give any impression that the data show general facts.
(7) Photographs or illustrations likely to induce misunderstanding or compromise the integrity of drugs must not be used.
(8) Care shall be taken to avoid copyright infringement or misunderstanding when sentences or expressions are quoted.
(9) Advertisements mainly showing only the name of a product shall include the

name (proprietary name), therapeutic category (product title), regulatory classification, generic name, and whether it is listed in the drug price list or not, together with the contact information to request materials related to the product.

(10) Only promotional printed materials and advertisements reviewed by the Sales Information Activity Audit Division (hereinafter referred to as the "Audit Division") shall be used.

4. Outsourcing

The Company may request healthcare professionals to give lectures, write, investigate, research, participate in lectures held by the Company, and provide training, etc., and pay them remuneration and expenses related to the requested operations. However, payment cannot be made if it is significantly expensive in light of the service provided.

5. Conduct of Post-marketing Safety Management Operation and Post-marketing Surveillance

The Company shall correctly recognize the purpose of post-marketing safety management operations and post-marketing surveillance, i.e., establishment of the method of proper use of drugs in a post-marketing setting, and conduct operations in compliance with related laws and regulations as well as self standards, and must not use it as the means of sales promotions.

6. Provision and Management of Drugs for Trial Use

Drugs for trial use are one of the means to provide pharmaceutical information. There are "drug samples" that show healthcare professionals the characteristics of drug appearance and "drugs for clinical trial use" for doctors to confirm/evaluate the quality, efficacy, safety, and formulation characteristics prior to use.

Both must be provided together with information on the relevant prescription pharmaceutical and in a minimum necessary amount. Since "drugs for clinical trial use" in particular are used in actual clinical practice, a strict management system shall be established and appropriately operated.

7. Conduct of Lecture Meetings, etc.

Lecture meetings held by the Company for healthcare professionals, etc., shall be intended to provide attendees with professional and academic/scientific information. The venue of lecture meetings, etc., and their locations shall be appropriate in terms of the purpose and located in Japan in principle. If foods/drinks are provided in association with lecture meetings, etc., such foods/drinks shall not be luxurious and shall not compromise the integrity of pharmaceutical companies. Monetary payment in association with lecture meetings shall be limited to travel expenses (transportation/accommodation, etc.) and lecture fees for persons who are involved with roles.

Travel expenses of accompanying persons shall not be paid, and such persons are not allowed to participate in social events.

On the other hand, when lecture meetings, etc., are planned to provide the general public other than healthcare professionals with information for disease enlightenment, such meetings shall be held in consideration of the Pharmaceutical and Medical Device Act and Standards for Adequate Advertisement of Drugs, etc.

8. Provision of Goods

The Company shall not provide healthcare professionals and medical institutions with goods likely to affect the proper use of drugs or goods likely to compromise the integrity of drugs.

9. Provision of Money

The Company shall not directly or indirectly provide healthcare professionals and medical institutions with money likely to affect the proper use of drugs.

10. Relationship with Fair Competition Code

The Company shall actively and strictly comply with the Fair Competition Code.

The Company shall not only show an attitude to comply with the Fair Competition Code but shall also act with a high sense of ethics.

11. Management of Promotion Code

(1) The Promotion Code shall be managed by the Audit Division and Sales Information Provision Activities Review/Audit Committee (hereinafter referred to as the "Review/Audit Committee").

(2) The Audit Division shall review whether promotional materials, etc., violate the Promotion Code beforehand based on advice from the Review/Audit Committee.

(3) The Audit Division shall regularly monitor whether the department and persons in charge of promotional activities conduct appropriate promotional activities or not, and also provide necessary guidance and supervision to the department and persons in charge.

(4) The Audit Division shall prepare necessary written procedures to conduct operations related to promotional activities, prepare operation records (including records of oral explanation, etc., during promotional activities), and appropriately retain the records.

(5) The Audit Division shall investigate and hear cases of potential violations of the Promotion Code based on complaints related to the Promotion Code, or at its own discretion. In the event of violation of the Promotion Code, the Audit Division may have the relevant person and the relevant department take corrective actions.

(6) In having the relevant person and the relevant department take the above actions, the Audit Division must give the person and department an opportunity to explain in writing or orally.

(7) The relevant person or the relevant department must cooperate for the investigation conducted by the Audit Division based on the above (5).