

# Compliance Regulations


**Version 2.0**



*310, Pangyo-ro, Bundang-gu, Seongnam-si,  
Gyeonggi-do, Republic of Korea*


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## CHAPTER 1. GENERAL PROVISIONS

### **Article 1. Objective**

The objective of “Compliance Regulations” (hereinafter referred to as the “Regulations”) shall be to provide guidelines with which officers and employees at SK biosciences Co., Ltd. (hereinafter referred to as the “Company”) perform their duties in compliance with the relevant laws and regulations such as: the “Monopoly Regulation and Fair Trade Act”; the “Pharmaceutical Affairs Act”; the “Medical Service Act”; the “Medical Device Act”, the “National Health Insurance Act”; the “Act on Fair Labeling and Advertising”, as well as codes and guidelines such as: the “Fair Competition Code on the Transaction of Pharmaceuticals” and operating guidelines of the Korea Pharmaceutical and Bio-Pharma Manufacturers Association approved by the Fair Trade Commission; the “Fair Competition Code on the Transaction of Medical Devices” and operating guidelines of the Korea Medical Devices Industry Association; and etc. (hereinafter referred to as the "Relevant Laws and Regulations").

### **Article 2. Scope of Application**

The Regulations shall apply to all officers and employees of the Company.

### **Article 3. Standard Operating Guideline**

The Company shall establish standard operating guidelines with respect to the details, reflecting the intent of the Regulations.

### **Article 4. Duties of Officer and Employee**

- ① Officers and employees shall comply with the Relevant Laws and Regulations to all activities related to business operations and performance of the Company.



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- ② Officers and employees shall actively cooperate with the instructions of the Compliance Officer and the office in charge to comply with the Relevant Laws and Regulations.
- ③ In case there is a suspicion that an officer or employee has violated Relevant Laws and Regulations in the performance of his/her duties, he/she must notify the Compliance Officer and the office in charge and have a prior consultation and review on the issue.
- ④ In case an officer or employee identifies a violation of the Relevant Laws and Regulations, he/she must immediately report the incident to the Compliance Officer.

## CHAPTER 2. ORGANIZATION AND ROLE

### Article 5. Office in Charge

- ① The Company shall have the Compliance Office as the Office in Charge of the Compliance Program operations to comply with the Relevant Laws and Regulations.
- ② The Office in Charge shall perform the following tasks:
  - A. Establish standard operating guidelines for complying with the Relevant Laws and Regulations;
  - B. Build operation plans of a variety of compliance programs, implement and evaluate their performance for complying with the Relevant Laws and Regulations;
  - C. Monitor compliance with the Relevant Laws and Regulations and investigate violations;
  - D. Establish and operate an education and training plan on the Relevant Laws and Regulations; and
  - E. Perform the tasks necessary to comply with other Relevant Laws and Regulations.

### Article 6. Compliance Officer

- ① The Company shall designate the Compliance Officer among executive officers who are not engaged in marketing activities.



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- ② The appointment and dismissal of the Compliance Officer shall be subject to the approval by the Representative Director.
- ③ The duties of the Compliance Officer shall be done in the way to secure the independence.
- ④ The Compliance Officer shall supervise the Office in Charge and play the following roles:
  - A. Establish and operate a compliance system for complying with the Relevant Laws and Regulations;
  - B. Plan and supervise operation tasks for complying with the Relevant Laws and Regulations;
  - C. Monitor compliance with the Relevant Laws and Regulations and report the findings to the Representative Director; and
  - D. Demand compliance with the Relevant Laws and Regulations and these Regulations, etc., and request for suspension, improvement or redress on violations, or sanctions against an officer or employee who conducted violations.

## Article 7. Preplanning Council

- ① The Company may operate a Preplanning Council (hereinafter referred to as the “Council”) to build an operation plan in accordance with the Relevant Laws and Regulations and to improve the efficiency and effectiveness of compliance activities complying with the Relevant Laws and Regulations.
- ② The Council shall consist of members who are head of the relevant offices depending on the case, and the head of the Council shall be the Compliance Officer. In case of absence of the Compliance Officer, the head of the Compliance Office shall act on his/her behalf, and in case of absence of the member, the deputy chief of the relevant office may be present.
- ③ If it is deemed necessary to discuss regarding the application of these Regulations, the person concerned in the matter may request the Office in Charge to convene a Council meeting.
- ④ The Office in Charge shall determine whether the matter needs to be discussed and



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reviewed by the Council. If necessary, the Office in Charge shall convene a Council meeting to conduct a discussion and review of the matter.

- ⑤ The matters discussed and reviewed by the Council shall be determined after the final approval of the Compliance Officer.
- ⑥ The Compliance Officer shall, if deemed necessary, report the matters discussed and reviewed by the Council to the executive officers of the relevant office or the Representative Director.

## CHAPTER 3. COMPLIANCE OPERATION

### Article 8. Preparation and Distribution of Compliance Guideline


- ⑦ The Office in Charge shall prepare and distribute the Compliance Guideline for complying with the Relevant Laws and Regulations.
- ① In case the Relevant Laws and Regulations are revised, the revised contents shall be reflected in the Compliance Guideline.

### Article 9. Compliance Education

- ① The Office in Charge may conduct compliance education session for the officers and employees at least once a year to enhance their awareness of compliance and may conduct education from time to time if necessary.
- ② Officers and employees who are exposed to high risks to violate the Relevant Laws and Regulations may be trained for more than two (2) hours semiannually.

### Article 10. Internal Audit for Compliance

- ① The Office in Charge shall regularly monitor the compliance of the officers and employees.
- ② The Office in Charge shall operate a report center so that an officer or employee can report any behavior that may violate or be likely to violate the Relevant Laws and Regulations or

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the Company policies related to fair trade.

### **Article 11. Evaluation and Reporting**

- ① The Office in Charge shall evaluate whether the compliance program is working effectively, report it to the Compliance Officer, and reflect it in the operation of the compliance program.
- ② The Compliance Officer may report the operating status of the compliance program to the Representative Director more than once semiannually.

### **Article 12. Document Management**

- ① The Office in Charge shall manage and supervise all documents related to the operation of the compliance program to ensure that they are systematically managed and maintained within the Company.
- ② The Office in Charge may have at least one (1) person in charge of document management for the systematic maintenance of documents related to the compliance program.


### **Article 13. Disclosure**

The Compliance Officer may voluntarily disclose the operation status of the compliance program to the stock exchange.


### **Article 14. Disciplinary Measures**

- ① In case a breach of the Regulations is found, the Company may report the responsible officer or employee to the Personnel Committee and may take an appropriate disciplinary measure against the officer or employee in accordance with the Company's regulations on reward and punishment.
- ② In case the Company suffers direct or indirect damage due to the breach of the Regulations by an officer or employee, the Company may take civil or criminal measures against the



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violator.

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**Addendum**

**Article 1. Date of Enforcement**

This Regulations shall be effective on and after July 1, 2018.

**Addendum**

**Article 1. Date of Enforcement**

This amended Regulations shall be effective on and after November 23, 2020.