SAMSUNG BIOEPIS
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# 2024 Methodological Note by SAMSUNG BIOEPIS

## for Disclosure of Transfers of Value (ToV)

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# 1. Introduction

## About SAMSUNG BIOEPIS

Samsung Bioepis is a biopharmaceutical company dedicated to unlocking the potential of biosimilar medicines and transforming the way biologic therapies are brought to patients. Our mission is reflected in our name, bio-epis; literally meaning life ('bio') and science ('episteme') in Greek. We want to enhance the lives of patients through our pioneering and innovative use of science and technology.

Samsung Bioepis was founded in 2012 and is headquartered in Incheon, Korea. Samsung Bioepis has developed one of the most expansive and rapidly advancing biosimilar medicines portfolios in the industry.

Samsung Bioepis is NON-MEMBER of European Federation of Pharmaceutical Industries and Associations (EFPIA). But, as a member of Korea Pharmaceutical Manufacturers Association (KPBMA), we voluntarily comply with all provisions of the EFPIA Code. We shall conduct business activities in accordance with the rules of the relevant country's pharmaceutical organization, if any, and if not, in accordance with the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Practice.

## Our Commitment

As a company with global operations, Samsung Bioepis will comply with all applicable laws and regulations including, but not limited to, those relating to the research, development, manufacturing, marketing, promotion, and product distribution in all of the countries where we conduct business activities.

In addition, we will adopt and follow industry codes of practice applicable to our business. No violations of laws and regulations will be tolerated.

Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA):
The Korea Pharmaceutical and Bio-Pharma Manufacturers Association is an organization representing the Korean pharmaceutical industry, established in 1945 for the purpose of 'improving national healthcare through the sustainable development of the pharmaceutical industry'. Membership extends beyond Korean pharmaceutical companies to encompass biotech firms specializing in digital therapeutics and artificial intelligence and multinational pharmaceuticals.
(https://www.kpbma.or.kr/english/aboutKPBMA)

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA):
IFPMA represents the innovative pharmaceutical industry at the international level and in official relations with the United Nations. IFPMA works closely with all public health stakeholders in the UN system, including the World Health Organization, World Trade Organization, and World Intellectual Property Organization. We also partner with governments, global health organizations, NGOs, civil society, patient groups, international hospital organizations, global foundations, and research and academic institutions.
(https://www.ifpma.org/about-us/)

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# 2. Overview of the EFPIA Requirements

### European Federation of Pharmaceutical Industries and Associations (EFPIA):

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the biopharmaceutical industry operating in Europe. Through its direct membership of 37 national associations, 40 leading pharmaceutical companies and a growing number of small and medium-sized enterprises, EFPIA's mission is to create a collaborative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy. (https://www.efpia.eu/about-us/)

### About the Disclosure Payments in the EFPIA Code

Collaboration between pharmaceutical industry and healthcare professionals (HCP) and healthcare organisations (HCO) benefits patients. It is a relationship that has delivered new vaccines and medicines and fosters the innovation that improves patients' lives. Furthermore, patient organisations (PO) play a critical role in Europe's healthcare: from prevention and awareness, through research and development, regulatory and HTA decision-making, to service design and outcomes measurement.

Bringing greater transparency to this already well-regulated and vital relationship, builds understanding of industry-PO and HCP/HCO collaboration and, in the context of increasing societal expectations on transparency, addresses directly public concerns about interactions between the medical community and the pharmaceutical industry. (https://www.efpia.eu/relationships-code/disclosure-of-payments/)

### Countries in Scope:

Countries with an EFPIA Member Association currently include the following 37 countries:
Austria, Belgium, Bosnia & Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Macedonia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom.

# 3. Definition

### Healthcare Professional (HCP)
Any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, sell or administer a pharmaceutical product.

### Healthcare Organization (HCO)
Any legal person/entity that is a healthcare, medical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation is in the world or through which one or more HCP provides services.

### Patient Organizations (PO)
A not-for-profit institution that primarily represents the interests and needs of patients, their families and/or caregivers

### Other Relevant Decision Maker (ORDM)
Someone could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who is not an HCP.

### Third Party
A legal person/entity or individual that represents a Company or interacts with other Third Parties on behalf of a Company or relating to the Company's Medicinal Product, such as distributors, wholesalers, consultants, contract research organisations, professional congress organisers, contracted sales forces, market research companies, advertising agencies, providers of services related to events, public relations services, non-clinical, non-interventional studies management services.

### Events
All professional, promotional, scientific, educational meetings, congresses, conferences, symposia, and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) organised or sponsored by or on behalf of a Company.

### Donations and grants
Providing funds, assets or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient to provide goods or services to the benefit of the donor in return.

### Sponsorship
Support provided by or on behalf of a Member Company, when permitted by law, as a contribution to support an activity (including an Event) performed, organised or created by an HCO/PO or any other Third Party.

### Collaborative Working
Working with other organisations to deliver initiatives which either enhance patient care or are for the benefit of patients or alternatively benefit the National Health Service (NHS) and, as a minimum, maintain patient care.

### Transfers of Value (ToV)

Direct and indirect transfers of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of Medicinal Products exclusively for human use. Direct ToV are those made directly by a Member Company for the benefit of a Recipient. Indirect ToV are those made on behalf of a Company for the benefit of a Recipient, or those made through a Third Party and where the Company knows or can identify the Recipient that will benefit from the ToV.

### Fair Market Value (FMV)

The value in arm's-length transactions, consistent with the general market value. 'General market value' means the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement.

### Fee for Services (FFS)

FFS is a method in which HCP or ORDM are paid for each service performed.

### Recipient

Any HCP/HCO/PO or ORDM as applicable per local requirements, in each case, whose primary practice, principal professional address or place of incorporation is in the world.

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# 4. Data Privacy and Protection for Disclosure

### Individual Data/Consent Handling Process

According to the Data Protection Act 2018 GDPR, Samsung Bioepis has obtained explicit informed consent for disclosure from HCP and ORDM. To meet obligations under the ABPI Code of Practice and other applicable law, Samsung Bioepis has efforts to provide the the Privacy Notice which explains how Samsung Bioepis manages private/individual data. The Privacy Notice has been delivered to HCP or ORDM with attaching to 'Informed Consent Form' or published on the Samsung Bioepis' webpage (http://www.samsungbioepis.com). Personal data including consent can be withdrawn if an HCP/ORDM wants to do at any moment. To withdraw personal data, Individual can request it to Samsung Bioepis Compliance with e-mail (cp.bioepis@samsung.com).

### Partial Consent

When an HCP/ORDM provides partial consent for disclosure, ToV information from Samsung Bioepis will be disclosed in the aggregate category, subject to applicable laws and may make misleading disclosure, unmet to the intent of transparency reporting system.

### Pre-Disclosure for Transparency Reporting

Samsung Bioepis provided pre-disclosure to HCP and ORDM on an individual level. The details of ToV and all related information for disclosure required by ABPI were sent. Prior to ABPI disclosure on 30$^{th}$ Jun 2024, each individual can verify and review the provided information whether it is accurate and clear via Disclosure Portal.

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# 5. Data Collection and Processing for Disclosure

| Categories | Scope |
|---|---|
| Contracts | Samsung Bioepis engages both one-year and multi-year contracts and payments could be executed after each service has finished within the total engagement period. |
| Tax & VAT | Basically, all payments and transfer of value to be disclosed include VAT where applicable. |
| Currency | All ToV are disclosed in EUR, GBP and USD as they have been executed to recipients. If required, ToV can be converted to local currency according to the standard for currency exchange rates in Samsung Bioepis' financial policy prior to report. |
| Cross Border Payments | ToV to HCP/HCO whose practice, professional address or place of incorporation is in Europe, are required to be disclosed in the country where the recipient has its principal practice. |
| Disclosure Period | Disclosure Period will be covered with a full required period by country laws and policies |
| Disclosure Time | Disclosure Time will be set with a specific date by country laws and policies |
| ToV Correction | HCP or HCO may request correction of published ToV that are found to be incorrect. In these cases, Samsung Bioepis will correct and re-publish these ToV. |
| ToV Dates | Samsung Bioepis will disclose direct/indirect payments and ToV based on the date the payment executed.<br>For [Cash Payment]<br>It is defined as the date of the payment was provided to the covered recipient<br>• Fees for Contracted Services (e.g. consulting, lecture)<br>• Grants, Donations and Sponsorships<br>• Research and Development<br>• Reimbursement for expenses by contract<br>For [Event Payment]<br>It is defined as the expense occurred date from start to end of event.<br>• Expenses for Contract Services by company (e.g. Accommodation, registration fee) |
| Language | Samsung Bioepis will basically make disclosure reports and methodology note in English. All materials can be made in other required language if required by each country code or law. |
| Local Identifiers | Samsung Bioepis should disclose the required information of 'Unique Identifier' for each HCP/HCO where disclosure is mandated. |

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# 6. Categories of Disclosures

The following types of ToV to stakeholders are disclosed by Samsung Bioepis.

| Categories | Types of ToV Included |
|---|---|
| ToV to HCP | Fees for Contracted Service<br>1) Speaker fee at a company-organized educational event<br>2) Consulting fee for advisory board meeting, development of educational materials, scientific or strategy consulting, participating in market research<br>3) Chairing a meeting<br>4) Fees related with research & development activities or market research<br>5) Registration fees and other expenses such as meals, transportation, and accommodation paid by a Company for scientific activities |
| ToV to ORDM | Fees for Contracted Service<br>1) Speaker fee at a company-organized educational event<br>2) Consulting fee for advisory board meeting, development of educational materials, scientific or strategy consulting, participating in market research<br>3) Chairing a meeting<br>4) Fees related with research & development activities or market research<br>5) Registration fees and other expenses such as meals, transportation, and accommodation paid by a Company for scientific activities |
| ToV to HCO | Fees for Contracted Service<br>1) Speaker fee at a company-organized educational event<br>2) Consulting fee for advisory board meeting, development of educational materials, scientific or strategy consulting, participating in market research<br>3) Chairing a meeting<br>4) Fees related with research & development activities or market research<br>5) Registration fees and other expenses such as meals and drinks, travel and accommodation paid by a Company for scientific activities<br><br>Grants and Donations<br>1) Research grant, donation or benefits for scientific purpose<br>2) Grant, product donation or benefits in kind provided to support public healthcare<br><br>Sponsorships<br>1) Registration fees and other expenses such as meals and drinks, travel and accommodation paid by a Company for scientific activities<br><br>Joint Working<br>1) Engagement with the National Health Service (NHS) or other organisations for enhancing and maintaining patient care |
| ToV to PO | Fees for Contracted Service<br>1) Speaker or consulting fee for educational event regarding disease awareness, patient healthcare, national healthcare services<br><br>Grants and Donations<br>1) Grant, product donation or benefits in kind provided to support public healthcare |

# 7. Appendix

## Sources/References

| Name | Document | Publication |
|---|---|---|
| UK ABPI Code of Practice | LINK: (https://www.abpi.org.uk/reputation/abpi-2021-code-of-practice/) | 2021 Ver. |
| EFPIA Code of Practice | LINK: (https://www.efpia.eu/relationships-code/the-efpia-code/) | 2019 Ver. |
| IFPMA Code of Practice | LINK: (https://www.ifpma.org/publications/ifpma-code-of-practice-2019/) | 2019 Ver. |
| KPBMA Code of Practice | LINK: (https://www.kpbma.or.kr/english/codeOfPractices) | 2014 Ver. |

## Contact

When you have any question or issues raised with this report,
Please contact Samsung Bioepis Compliance (cp.bioepis@samsung.com).

We will respond to any inquiries and adjust the required results from our review.
Updated information will be published in the next material or immediately if possible.