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Medicines for Europe (MFE) HCP/HCO/PO Disclosure Transparency Requirements

Samsung Bioepis Methodology Note

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1. Overview of the MFE Requirements

Medicines for Europe (MFE):
Medicines for Europe represents the pharmaceutical companies supplying the largest share of medicines across Europe and is the voice of the generic, biosimilar and value added industries. As a leading partner for better healthcare, we aim to increase the health and wellbeing of all Europeans through better access to high quality medicines.

The call for Transparency:
Transparent relations and interactions between companies and Healthcare Professionals/Organizations and Patient Organizations assist informed decision-making and help to prevent unethical and illegal behavior. The Medicines for Europe Code therefore requires Medicines for Europe member companies to disclose Transfers of Value that could potentially pose a conflict of interest, or to encourage the recipients of the transfers of value to disclose them, where such disclosure would be in the best interest of patients or the public, further specified below. Such disclosure shall include Transfers of Value made by a third party on behalf of a Medicines for Europe member company for the benefit of a recipient and where the Medicines for Europe member company knows or is informed about the recipient who will benefit from the Transfer of Value.

Countries in Scope:
Countries with an MFE Member Association currently include the following 28 EU countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Russia, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom.

2. Decisions

The purpose of this methodology note document is to provide guidance on Samsung Bioepis-specific decisions that explain the disclosure data. This document highlights the decisions that drive our collection, aggregation and reporting process.

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.
Consent	Samsung Bioepis respects that consent should be obtained from Healthcare professionals for the disclosure of transfer of value, if required under the relevant data protection laws and regulations. In line with this, Samsung Bioepis is collecting consent at the first point of first engagement and also notifying the disclosure of transfer of value to individual Healthcare professionals concerned.
Currency	All payments and transfers of value will be disclosed in EUR, GBP and USD as they have been executed to recipients .
Transfer of values correction	HCPs or HCOs may request correction of published transfers of values that are found to be incorrect. In these cases, Samsung Bioepis will correct and re-publish these transfers of values.
Transfer of Value Dates	Samsung Bioepis will disclose payments and transfers of value based on the date the payment executed.
Language	Disclosure shall be made in English.

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3. Submission Requirements

Disclosure Method	Samsung Bioepis will publish the disclosure file on the Samsung Bioepis website for the following countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Russia, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom.
Disclosure Period	Each reporting period shall cover a full calendar year.
Timing of Disclosure	At the latest by June 30th.

4. Categories for Disclosure

Description	**Types of Transfer of Value Included**
Transfer of Value to Patient Organizations	- Support: financial and in-kind support - Fee for services: contracted services per Patient Organization, including a description of the nature of the Transfer of Value (educational summer camp, disease awareness world day, development of information brochures for an awareness campaign, etc.) and the amount provided.
Transfers of Value to Healthcare Professionals	- Fees for services and consultancy: aggregated honoraria (excluding expenses such as meals and drinks, travel and accommodation) paid by a Company to a Healthcare Professional in exchange for the provision of services, such as serving as an expert on an advisory board, speaking at a company-organized educational event, participating in a focus group, etc. Fees paid in connection with research & development activities or market research, are excluded from the scope of this disclosure.
Transfers of Value to Healthcare Organizations	- Fees for services and consultancy: aggregated honoraria (excluding expenses such as meals and drinks, travel and accommodation) paid by a Company to a Healthcare Organization in exchange for the provision of services, such as serving as an expert on an advisory board, speaking at a company-organized educational event, participating in a focus group, etc. Fees paid in connection with research & development activities or market research, are excluded from the scope of this disclosure. - Grants and donations: aggregated monetary amounts and a brief description of the nature of the grant or donation (e.g. research grant, equipment donation, product donation, etc.)

5. Definitions

Applicable rules and requirements
All laws (including national laws), regulations, codes of practices and standards that apply to a company or transaction in any given location or circumstance.

Medicines for Europe Members
Medicines for Europe member companies (including Medicines for Europe member company affiliates) and Medicines for Europe national associations (including Medicines for Europe national associations affiliate members).

Healthcare Community
Healthcare Professionals, Healthcare Organizations, Patients and Patient Organizations.

Patient Organizations (PO)
Collectively, means those donations and grants (either cash or benefits in kind) within the scope of Article 11 of the HCP Code.

Healthcare Professional (HCP)
Any natural person that is a doctor, a member of medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product. For the avoidance of doubt, the definition of Healthcare Professional includes: (i) any official or employee of a government agency or other organization (whether in the public or private sector) that may prescribe, dispense, purchase or administer medicinal products and (ii) any employee of a pharmaceutical company whose primary occupation is that of a practicing Healthcare Professional, but excludes (x) all other employees of a pharmaceutical company and (y) a wholesaler or distributor of medicinal products.

Healthcare Organization (HCO)
Any entity (i) 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 or (ii) through which one or more Healthcare Professionals provide healthcare services. For the avoidance of doubt, wholesalers, distributors, and similar commercial intermediaries are not considered Healthcare Organizations.

6. Appendix

Sources Name	Document	Edition
Medicines for Europe – Code of Conduct	The guidelines on interactions with the Healthcare Community, which aims to set a framework of standards and principles that promotes trust, responsible behavior, and respect, between pharmaceutical companies and the Healthcare Community, including Healthcare Professionals, Healthcare Organizations, patients and Patient Organizations.	Jan, 2016
Medicines for Europe – Code of Conduct Q&A	Relevant questions and answers from the Code of Conduct	Version 3