Approval of the Commitment Plan Submitted by SYSMEX CORPORATION

February 13, 2025
Japan Fair Trade Commission

The Japan Fair Trade Commission (hereinafter referred to as the "JFTC") has investigated SYSMEX CORPORATION (hereinafter referred to as "Sysmex") in accordance with the provisions of the Antimonopoly Act (hereinafter referred to as the "Act"), and suspected that Sysmex's conduct described below might violate the Article 19 (falling under paragraph (10) [Tie-in Sales]) of the Act.

Recognizing that competition would be promptly restored, through the Commitment Procedure, by measures to be swiftly taken by Sysmex to ensure that the conduct has been eliminated, the JFTC issued the Notice of Commitment Procedures to Sysmex on January 16, 2025, pursuant to Article 48-6 of the Act.

Sysmex submitted the Commitment Plan to the JFTC for an approval of measures necessary to ensure that the conduct described below has been eliminated, pursuant to the Article 48-7, paragraph (1) of the Act. The JFTC today approved the Commitment Plan, pursuant to the Article 48-7, paragraph (3) of the Act recognizing that the plan is sufficient to ensure that the conduct has been eliminated and expected to be reliably implemented (Note 1) (Note 2).

This Commitment Plan includes a five-year implementation period for the commitment measures and the entrustment of monitoring the overall implementation of these measures to a third party (Note 3).

It is noted that today's approval does not mean that Sysmex's conduct violated the Act.

(Note 1) An approval of the Commitment Plan is an administrative disposition under the Act.

(Note 2) The JFTC is to render a decision to rescind the approval pursuant to the Article 48-9, paragraph (1) of the Act and resume the investigation procedure conducted before the Notice of Commitment Procedures is issued, for instance, if the JFTC recognizes that the Commitment Plan is not being conducted according to the approved Commitment Plan.

(Note 3) At the regular press conference of the Secretary General held on July 3, 2024, measures to ensure more efficient and effective implementation of the Commitment Procedures were announced.

1. Overview of Sysmex's Business

(1) Sysmex, headquartered in Kobe, is a company engaged in the manufacturing and sale of medical devices, etc. Since 1984, it has been producing and selling blood coagulation analyzers (Note 4).

(2) Sysmex directly promotes the blood coagulation analyzers (hereinafter referred to as "specific blood coagulation analyzers") and the reagents (hereinafter referred to as "designated reagents") that it manufactures to hospitals and other medical institutions and sells them through wholesalers.

(3) Sysmex holds the largest market share nationwide for blood coagulation analyzers in terms of both sales volume and sales value.

(Note 4) A "blood coagulation analyzer" refers to a medical device used for measuring blood coagulation.

(4) Blood coagulation analyzers that are manufactured and sold in Japan, are generally capable of using not only coagulation reagents produced by the analyzer manufacturers but also those produced by other companies.

Additionally, some manufacturers of coagulation reagents do not produce blood coagulation analyzers and engage solely in the manufacturing and sale of coagulation reagents.

2. Overview of the Alleged Conduct

Since at least August 2019 and until around July 2024, Sysmex maintained a fundamental policy requiring the use of its designated reagents for measuring "D-dimer" or "FDP" (Note 5) with specific blood coagulation analyzers, even though reagents from other manufacturers could be used. In line with this policy, when supplying these analyzers to hospitals and other medical institutions, Sysmex conditioned its supply on the exclusive use of its designated reagents, effectively compelling them to purchase these reagents alongside the analyzers.

(Note 5) D-dimer and fibrin/fibrinogen degradation products (FDP) are substances produced during the breakdown of blood clots. When a blood vessel is damaged due to an accident or injury, a clot forms to stop the bleeding. After the vessel is repaired, the clot dissolves, generating these substances. Measuring their levels is used in the diagnosis of various conditions, including thrombosis, aneurysms, myocardial infarction, and cerebral infarction.

3. Concept under the Act

As a result of the conduct described in section 2, it is considered that some hospitals and other medical institutions were effectively forced to purchase Sysmex's designated reagents. This led some to discontinue purchasing non-Sysmex reagents they had previously used for measuring "D-dimer" or "FDP."

Given Sysmex's strong position in the blood coagulation analyzer market, the conduct described in Section 2 could lead to the exclusion of suppliers of non-Sysmex reagents from transactions with hospitals and other medical institutions or the reduction of their opportunities

for such transactions when providing reagents for “D-dimer” or “FDP” testing.

4. Overview of the Commitment Plan

(1) Resolving following matters at a meeting of Board of directors.

(a) To confirm that the conduct described in section 2 above have been ceased.

(b) To decide not to engage in conduct similar to those described in section 2 regarding its blood coagulation analyzers and reagents and to implement this measure for the next five years.

(2) Notifying hospitals and other medical institutions that use the specific blood coagulation analyzers, as well as wholesalers selling these analyzers, of the measures taken based on (1). Additionally, ensuring that these measures are disseminated to the relevant executives and employees involved in the sales of specific blood coagulation analyzers and designated reagents.

(3) Refraining from engaging in conduct similar to those described in section 2 regarding its blood coagulation analyzers and reagents and implementing this measure for the next five years.

(4) Taking necessary measures to perform following items:

(a) Creating codes of conduct in accordance with the Act related to the sale of blood coagulation analyzers and reagents and disseminating these codes to executives and employees involved;

(b) Periodic training for its executives and employees and periodic audits by legal section for compliance with the Act regarding the sale of blood coagulation analyzers and reagents.

(c) Establishment of a contact point for handling inquiries from hospitals and other medical institutions purchasing its blood coagulation analyzers and reagents regarding conduct that potentially violate the Act.

(5) Delegating the monitoring of the implementation of the measures described in (1) through (4) above to a third party, limited to those approved by the JFTC.

(6) Requiring the third party entrusted under (5) to report to the JFTC on the implementation status of the measures described in (1), (2) and (4).

(7) Requiring the third party entrusted under (5) to report annually to the JFTC, for the next five years, on the implementation status of the measures described in (3) and the measures taken based on (4)(b).

The JFTC recognized that the Commitment Plan above would conform to all the approval

requirements, and approved the Commitment Plan.

* This announcement is a tentative translation. Please refer to the original text written in Japanese.