[Translation]

Investigation Report

July 22, 2024

Fact-Finding Committee
of Kobayashi Pharmaceutical Co., Ltd.

July 22, 2024

To: Board of Directors of Kobayashi Pharmaceutical Co., Ltd.

Fact-Finding Committee
of Kobayashi Pharmaceutical Co., Ltd.

Committee Chairperson	Makoto Kaiami
Committee Member	Mikinao Kitada
Committee Member	Kengo Nishigaki

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Terms and Definitions Used in this Report[1]

Terms and Definitions	Details
Major Entity Names, Personal Names and Company Names	
Outside Director Ariizumi	Ms. Chiaki Ariizumi, Director
Full-time Audit and Supervisory Board Member Kawanishi	Mr. Takashi Kawanishi, Audit and Supervisory Board Member
Gunze	GUNZE LIMITED
Kobayashi Pharmaceutical	Kobayashi Pharmaceutical Co., Ltd.
Chairman & CEO Kobayashi	Mr. Kazumasa Kobayashi, Representative Director, Chairman of the Board and Chief Executive Officer
President & COO Kobayashi	Mr. Akihiro Kobayashi, Representative Director, President and Chief Operating Officer
Fact-Finding Committee/Committee	Committee that the BOD of Kobayashi Pharmaceutical decided to establish on April 26, 2024 and commissioned to conduct (i) an investigation into the factual events that took place after the cases were reported, and (ii) a careful examination of Kobayashi Pharmaceutical's internal control system and quality control system
Outside Directors	Individually or collectively, the four outside directors (Outside Director Kunio Ito, Outside Director Kaori Sasaki, Outside Director Chiaki Ariizumi, and Outside Director Yoshiro Katae)
Inside Directors	Individually or collectively, the three inside directors (Chairman & CEO Kobayashi, President & COO Kobayashi, and Senior Executive Director Yamane)
Full-time Audit and Supervisory Board Members	Individually or collectively, two full-time Audit and Supervisory Board members (Full-time Audit and Supervisory Board Member Yamawaki and Full-time Audit and Supervisory Board Member Kawanishi)
Outside Audit and Supervisory Board Members	Individually or collectively, two outside Audit and Supervisory Board Members (Outside Audit and Supervisory Board Member Hatta and Outside Audit and Supervisory Board Member Moriwaki)
Outside Officers	Collectively, the Outside Directors and the Outside Audit and Supervisory Board Members
Outside Audit and Supervisory Board Member Hatta	Ms. Yoko Hatta, Audit and Supervisory Board Member
Meitanhompo	Meitanhompo Co., Ltd.
Outside Audit and Supervisory Board Member Moriwaki	Mr. Sumio Moriwaki, Audit and Supervisory Board Member
Senior Executive Director Yamane	Mr. Satoshi Yamane, Senior Executive Director
Full-time Audit and Supervisory Board Member Yamawaki	Mr. Akitoshi Yamawaki, Audit and Supervisory Board Member
Medical Doctor A	Medical Doctor A at Hospital α, located in the Kyushu Region
Medical Doctor B	Medical Doctor B at Hospital β, located in the Kanto Region
Medical Doctor C	Medical Doctor C at Hospital γ, located in the Kinki Region
Attorneys Q and R	Collectively, attorney Q and attorney and medical doctor R
Medical Doctor S	Medical Doctor S at hospital affiliated with a national university in Japan

[1] Unless specifically indicated in this report, the positions in this report are those as of March 22, 2024.

Terms and Definitions	Details
GOM	Group Operating Meeting
PMDA	Pharmaceuticals and Medical Devices Agency
Feb. 5 Ad-hoc Meeting	Ad-hoc meeting held with persons concerned from various departments within the Pharmacovigilance & Consumer Relations Division at 12:00 p.m. on Monday, February 5
Feb. 6 Monthly Meeting	Monthly meeting held between the Pharmacovigilance & Consumer Relations Division and President & COO Kobayashi on Tuesday, February 6
Feb. 13 GOM	Regular GOM held on Tuesday, February 13
Feb. 20 GOM	Regular GOM held on Tuesday, February 20
Feb. 21 Audit and Supervisory Board Meeting	Audit and Supervisory Board meeting held on Wednesday, February 21
Feb. 22 Medical Doctor Interview	Interview between Kobayashi Pharmaceutical and Medical Doctor B held on Thursday, February 22
Feb. 26 GOM	Regular GOM held on Tuesday, February 26
Feb. 29 Medical Doctor Interview	Interview between Kobayashi Pharmaceutical and Medical Doctor A held on Thursday, February 29
Mar. 4 TEAM-F Meeting	Regular TEAM-F meeting (a meeting held monthly at which the Representative Director, President and Chief Operating Officer, the Senior Executive Director and full-time Audit and Supervisory Board members attend) held on Monday, March 4
Mar. 5 GOM	Regular GOM held on Tuesday, March 5
Mar. 6 External Expert Consultation	Consultation with Attorney & Medical Doctor P held from 11:30 a.m. to 1:00 p.m. on Wednesday, March 6
Mar. 12 GOM	Regular GOM held on Tuesday, March 12
Mar. 13 External Expert Consultation	Consultation with attorney Q held through an online meeting from 5:30 p.m. to 8:00 p.m. on Wednesday, March 13
Mar. 18 BRM	Regular BRM meeting (a meeting held twice a month at which the Representative Director, Chairman of the Board and Chief Executive Officer, the Representative Director, President and Chief Operating Officer, and the Senior Executive Director attend) held on Monday, March 18
Mar. 19 GOM	Regular GOM held on Tuesday, March 19
Terms Related to this Investigation	
Peak X	Unknown peak, which indicated that there was a possibility that a component which Kobayashi Pharmaceutical did not intentionally include was contained in a portion of the lots, including in the production lots previously mentioned in 3.8.3 (H306 and H3017), which were the product lots that the patients in each of the Cases had either consumed or possibly consumed
Medical Doctor Interviews	Collectively, the Feb. 22 Medical Doctor Interview and the Feb. 29 Medical Doctor Interview
Interpretation	Interpretation that “only when the causal relationship is clear”
Feb. 13 to Mar. 19 GOMs	Collectively, the GOMs held a total of six times, once a week, from Tuesday, February 13 to Tuesday, March 19
Cases	Cases of kidney problems that occurred after ingestion of the Product
Product	“Beni-koji Choleste-Help”
Investigation	Investigation of facts related to the Issue conducted by the Committee, which was commissioned by the BOD
Notification Guidelines	“Guidelines on Notification of Foods with Function Claims”

Terms and Definitions	Details
	(Revised on September 29, 2023) (CFL Notification No. 543) of the Consumer Affairs Agency that constitute the criteria for reporting health damage regarding Foods with Function Claims to the Consumer Affairs Agency
Press Release	Press release titled "Request for discontinuation of use of Red Yeast Rice related products and notice of voluntary collection" and dated March 22, 2024 announcing that Kobayashi Pharmaceutical would implement a voluntary collection of the Three Beni-koji Related Products
Three Beni-koji Related Products	"Beni-koji Choleste-Help," "Naishi-Help + Cholesterol," and "Nattou-Kinaze SaraSara tablet GOLD" that are three kinds of red yeast rice related products sold by Kobayashi Pharmaceutical
Issue	Issue relating to the occurrence of kidney problems caused by ingestion of "Beni-koji Choleste-Help"
B-to-B or B-to-B Business	Business to Business
B-to-C or B-to-C Business	Business to Consumer
Terms Related to Organizations and Regulations, Etc. of Kobayashi Pharmaceutical	
Pharmacovigilance Group	Pharmacovigilance Group of the Pharmacovigilance Department of the Pharmacovigilance & Consumer Relations Division
Pharmacovigilance Department	Pharmacovigilance Department of the Pharmacovigilance & Consumer Relations Division
Osaka Plant	Osaka Plant of Kobayashi Pharmaceutical
Customer Relations Office	Customer Relations Office of the Pharmacovigilance & Consumer Relations Division
Kinokawa Plant	Kinokawa Plant of Meitanhompo
New Product and Business Development Department	New Product and Business Development Department of the Central R&D Laboratory
Quality Assurance Group (Japan)	Quality Assurance Group (Japan) of the Quality Assurance Department of the Pharmacovigilance & Consumer Relations Division
Food Department	Food Department of the Healthcare Products Headquarters
Food R&D Group	Food R&D Group of the Food Department of the Healthcare Products Headquarters
Direct Marketing Division	Direct Marketing Division of the Healthcare Products Headquarters
Direct Marketing Department	Direct Marketing Department of the Direct Marketing Division of the Healthcare Products Headquarters
BOD	Board of Directors of Kobayashi Pharmaceutical
Quality Assurance Department	Quality Assurance Department of the Pharmacovigilance & Consumer Relations Division
Legal and Intellectual Property Department	Legal and Intellectual Property Department of the Sustainability Management Headquarters
Collection Rules	Product Collection Rules, and the Flow for Determining Product Collections
Reporting Flowchart	"Flowchart from the Collection of Health Damage Information to the Implementation of Measures" relating to Foods with Function Claims

1 Outline of the Investigation by the Fact-Finding Committee

1.1 Background, Etc. of the Establishment of the Fact-Finding Committee

From mid-January 2024 onwards, Kobayashi Pharmaceutical Co., Ltd. ("**Kobayashi Pharmaceutical**") received reports (case reports) that instances of kidney problems, etc. had occurred with respect to certain customers who ingested "Beni-koji Choleste-Help," a red yeast rice related product sold by Kobayashi Pharmaceutical. Subsequently, Kobayashi Pharmaceutical conducted an ingredient analysis of the "Beni-koji Choleste-Help" product and the red yeast rice ingredients that were used for this product, as a result of which it was found that some of the red yeast rice ingredients may have contained components that Kobayashi Pharmaceutical did not anticipate. Therefore, on March 22, 2024, Kobayashi Pharmaceutical issued a press release[2] (the "**Press Release**") to request customers to discontinue the use of three kinds of red yeast rice related products[3] sold by Kobayashi Pharmaceutical (the "**Three Beni-koji Related Products**"), including "Beni-koji Choleste-Help" (the "**Product**"), and the red yeast rice ingredients[4] used in the Three Beni-koji Related Products, and that Kobayashi Pharmaceutical would implement a voluntary collection of the Three Beni-koji Related Products (the series of related issues that arose during this period are hereinafter referred to as the "**Issue**").

In response to the Issue, the Board of Directors of Kobayashi Pharmaceutical (simply, the "**BOD**") decided to conduct an investigation led by the BOD and subsequent verification regarding the series of responses taken by Kobayashi Pharmaceutical with respect to the Issue. The BOD is composed of a total of seven members, three of whom are inside directors, namely Mr. Kazumasa Kobayashi, who is the Representative Director, Chairman of the Board and Chief Executive Officer ("**Chairman & CEO Kobayashi**"), Mr. Akihiro Kobayashi, who is the Representative Director, President and Chief Operating Officer ("**President & COO Kobayashi**"), and Mr. Satoshi Yamane, who is the Senior Executive Director ("**Senior Executive Director Yamane**"), and four of whom are outside directors. For the purpose of ensuring the independence and objectivity of the BOD's subsequent verification, the BOD deemed that the three inside directors had special interests in this matter and thus decided that the three inside directors would not

[2] This refers to the press release titled "Request for discontinuation of use of Red Yeast Rice related products and notice of voluntary collection" and dated March 22, 2024.
[3] This refers to "Beni-koji Choleste-Help," "Naishi-Help + Cholesterol," and "Nattou-Kinaze SaraSara tablet GOLD."
[4] The ingredients used in the Three Beni-koji Related Products are also sold by Kobayashi Pharmaceutical Value Support Co., Ltd. to other companies.

participate in deliberations or resolutions in the subsequent verification regarding the Issue, and only the remaining four outside directors would proceed with the investigation and verification.

In addition, the BOD regarded the following as the key objectives for the verification regarding the Issue: (i) an investigation into the factual events that took place after the cases were reported,[5] (ii) a careful examination of the internal control system and quality control system of Kobayashi Pharmaceutical, (iii) verification of conformity with laws and regulations, and (iv) determination of whether the timing of the public announcement was appropriate. Then, on April 26, 2024, the BOD decided to establish a fact-finding committee (the "**Committee**") in order to conduct independent, objective, and effective investigations and verification as soon as possible with respect to, among the above key objectives, (i) an investigation into the factual events that took place after the cases were reported, and (ii) a careful examination of internal control system and quality control system of Kobayashi Pharmaceutical, as these will form the foundation of the subsequent verification regarding the series of responses taken. Kobayashi Pharmaceutical established the Committee, the members of which are three attorneys-at-law who do not have any particular special interest in Kobayashi Pharmaceutical. Specifically, the BOD commissioned the Committee to conduct (i) an investigation into the factual events that took place after the cases were reported and (ii) a careful examination of the internal control system and quality control system of Kobayashi Pharmaceutical (the investigation of facts related to the Issue conducted by the Committee, which was commissioned by the BOD, is hereinafter referred to as the "**Investigation**").

1.2 Composition, Etc. of the Committee

The composition of the Committee is as follows. None of the members of the Committee have any particular special interest in Kobayashi Pharmaceutical.

Committee Chairperson: Attorney-at-law Makoto Kaiami, Otemachi Law Office
(Former President of the Tokyo District Court and Chief Judge at the Tokyo High Court)

Committee Member: Attorney-at-law Mikinao Kitada, Kitada Mikinao Law Office
(Former Superintending Prosecutor at the Osaka High Public Prosecutors Office)

[5] This specifically refers to the investigation into the factual events that took place during the period from the time when Case 1 was reported in mid-January 2024 to the time when the Press Release was issued on March 22, 2024.

Committee Member: Attorney-at-law Kengo Nishigaki, GI&T Law Office

The Committee also appointed Attorneys-at-law Yuji Yamamoto and Ryunosuke Chinen, both of whom belong to GI&T Law Office, to assist in its investigation.

Although the Committee formulated the basic plan for its investigation by itself and carried out its investigation in accordance with that basic plan, in order to carry out the Investigation in a flexible and prompt manner, the Committee also referred to the results of the ascertainment of facts by attorneys who belong to Mori Hamada & Matsumoto ("**MHM**"),[6] which was retained by Kobayashi Pharmaceutical to handle the Issue. The Committee also had attorneys who belong to MHM conduct, as an investigation for the Committee, a part of the ascertainment of facts and the summarization thereof and other related works. The Committee ensured the independence, objectivity, and effectiveness of the Investigation by leading the Investigation and proactively conducting the Investigation and critically verifying the results of the ascertainment of facts and other work conducted by the attorneys who belong to MHM.

1.3 Investigation Period and Investigation Methods, Etc.

The Committee was established on April 26, 2024, and it conducted the Investigation from that day until July 22, 2024. The primary methods of the Investigation included analyses and careful examinations of relevant documents and other materials, interviews, and digital forensic investigations, the details of which are described in **Attachment 1.3**.

1.4 Limitations of the Investigation

The Investigation was conducted to form a foundation for the BOD to conduct subsequent verification regarding how Kobayashi Pharmaceutical responded to the Issue, and it was not a comprehensive investigation into all instances of misconduct or inappropriate acts that took place at Kobayashi Pharmaceutical. In addition, there were

[6] The attorneys who belong to MHM have been providing legal advice to Kobayashi Pharmaceutical on how to respond to the Issue. However, as stated in 3.9.3 below, the request from Kobayashi Pharmaceutical to MHM for its advice on this Issue was not made until March 19, 2024, which was immediately prior to the publication of the Press Release, and thus the content of the advice or other assistance provided by MHM are fundamentally not the main subject of the Investigation. Therefore, the Committee reached a conclusion that the use of the results of ascertainment of facts and other work conducted by the attorneys who belong to MHM would not immediately impede the independence or the objectivity of the Committee.

certain limitations and constraints in the Investigation, including limitations due to its being a voluntary investigation and time constraints.

In other words, unlike an investigation conducted by a law enforcement agency, where compulsory disposition is possible, the Investigation was based on the voluntary cooperation by the parties concerned. Therefore, the Committee cannot deny the fact that the Investigation is naturally influenced by the degree of cooperation provided by the parties concerned. In addition, due to the nature of a voluntary investigation, the means of verifying the authenticity, completeness, comprehensiveness, and the like of the content of interviews and the materials subject to the investigation were also limited.

Furthermore, the Investigation was conducted during the investigation period specified above, and therefore was subject to certain time constraints.

Mainly due to the abovementioned limitations and constraints in the Investigation, the Committee cannot deny the possibility that the results of the Investigation could have been different from those contained in this report if certain investigation methods that the Committee was not able to use in this Investigation could have been used, and therefore, the Committee does not guarantee that the investigation results are complete.

2 Overview, Etc. of Kobayashi Pharmaceutical

2.1 Overview of Kobayashi Pharmaceutical

An overview of Kobayashi Pharmaceutical is as follows.

Company Name	Kobayashi Pharmaceutical Co., Ltd.
Date of Establishment	August 22, 1919
Amount of Stated Capital	3,450 million yen
Exchanges on which Shares are Listed	Prime Market of the Tokyo Stock Exchange
Fiscal year-end	December 31
Representatives	Kazumasa Kobayashi, Representative Director, Chairman of the Board and Chief Executive Officer Akihiro Kobayashi, Representative Director, President and Chief Operating Officer
Address of Head Office	4-10, Doshomachi 4-chome, Chuo-ku, Osaka-shi, Osaka
Description of Business	Manufacturing and sales of pharmaceutical products, quasi-pharmaceutical products, deodorizing air fresheners, and sanitary products etc.

2.2 Organizational Structure of Kobayashi Pharmaceutical

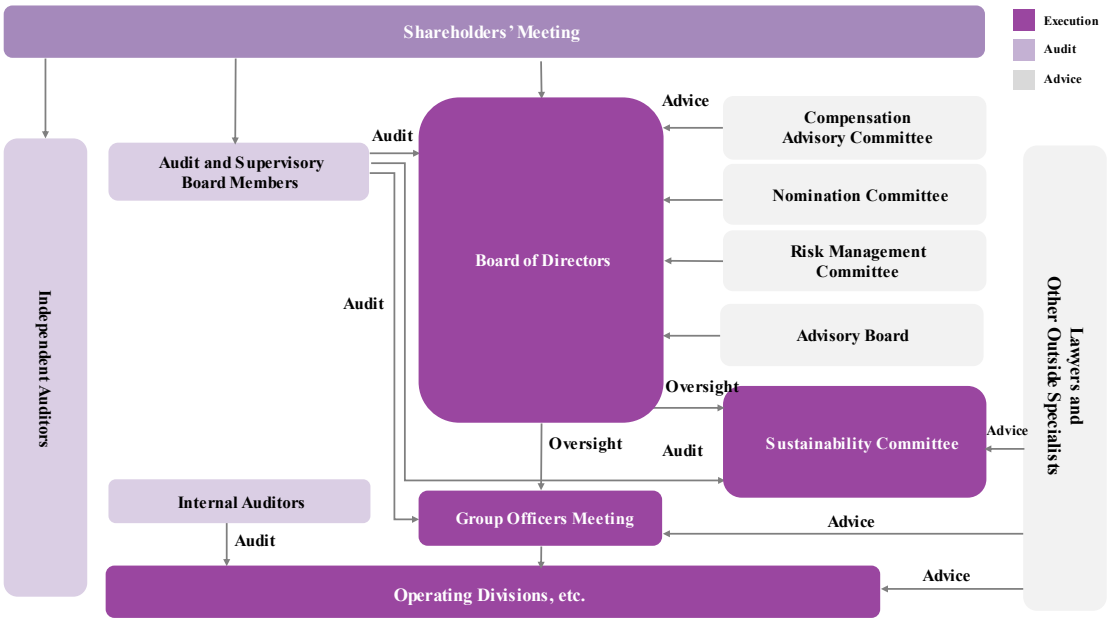
The organizational structure of Kobayashi Pharmaceutical as of January 1, 2024 is as described in **Attachment 2.2**.

2.3 Governance System of Kobayashi Pharmaceutical

2.3.1 Overview of the Governance System

According to the website [7] of Kobayashi Pharmaceutical, the overview of the governance system of Kobayashi Pharmaceutical as of January 1, 2024 is as follows.

[7] https://www.kobayashi.co.jp/contribution/governance/governance.html



2.3.2 Board of Directors

The BOD of Kobayashi Pharmaceutical holds regular meetings once a month in principle and extraordinary meetings as needed.

The BOD is expected to make decisions on the matters deliberated at the Group Operating Meeting (which is a meeting body called GOM for short, and further described in 2.3.4 below; the "**GOM**") and the important management matters, and to perform monitoring functions by evaluating the progress of material matters so decided.

The primary matters to be resolved by the BOD are basic matters concerning management (including decisions on basic policies for internal control systems), matters concerning the general meeting of shareholders, personnel, organization, assets, finances, and directors, important matters concerning corporate governance, important matters concerning reputational risk, and important matters concerning compliance (referred to as "Matters to be submitted to the Board of Directors" in the Regulations for Board of Directors). In addition, the primary matters to be reported to the BOD are important matters concerning the matters resolved by the GOM, important matters concerning operations and accounting, important matters concerning corporate governance, and the risk management system and its operation status.

The BOD is composed of a total of seven members, three of whom are inside directors, namely Chairman & CEO Kobayashi, President & COO Kobayashi and Senior Executive Director Yamane (those three inside directors are hereinafter individually or collectively

referred to as "**Inside Directors**"), and four of whom are outside directors, namely Outside Director Kunio Ito, Outside Director Kaori Sasaki, Outside Director Chiaki Ariizumi, and Outside Director Yoshiro Katae (those four outside directors are hereinafter individually or collectively referred to as "**Outside Directors**"). The outside directors account for a majority of the BOD.

Kobayashi Pharmaceutical adopted an executive officer system. While President & COO Kobayashi and Senior Executive Director Yamane concurrently serve as executive officers, Chairman & CEO Kobayashi does not concurrently serve as an executive officer, but serves as a chairman of the Board of Directors as Chairman of the Board and Chief Executive Officer. As such circumstances indicate, among the directors, President & COO Kobayashi and Senior Executive Director Yamane mainly execute the operations. Chairman & CEO Kobayashi does not participate in the GOM, but with respect to the material management matters, he reflects his intention in the management by giving advice on Kobayashi Pharmaceutical's execution of business.

2.3.3 Audit and Supervisory Board

The Audit and Supervisory Board of Kobayashi Pharmaceutical holds a meeting once a month in principle and may hold extraordinary meetings as needed.

The purpose of the Audit and Supervisory Board is to receive reports, hold discussions, and make resolutions on important matters concerning auditing (Article 3 of the Regulations for Audit and Supervisory Board). It is stipulated in the Regulations for Audit and Supervisory Board that if the Audit and Supervisory Board receives a report from a director to the effect that such director has discovered a fact that may cause significant damage to the company, the Audit and Supervisory Board shall conduct the necessary investigations and take the appropriate measures according to the circumstances (Article 15.1 of the Regulations for Audit and Supervisory Board).

The Audit and Supervisory Board is composed of a total of four members, two of whom are full-time Audit and Supervisory Board members, namely Akitoshi Yamawaki ("**Full-time Audit and Supervisory Board Member Yamawaki**") and Takashi Kawanishi ("**Full-time Audit and Supervisory Board Member Kawanishi**") (those two full-time Audit and Supervisory Board members are hereinafter individually or collectively referred to as "**Full-time Audit and Supervisory Board Members**"), and two of whom are outside Audit and Supervisory Board Members, namely Yoko Hatta ("**Outside Audit and Supervisory Board Member Hatta**") and Sumio Moriwaki ("**Outside Audit and Supervisory Board Member Moriwaki**") (those two outside Audit and Supervisory

Board Members are hereinafter individually or collectively referred to as "**Outside Audit and Supervisory Board Members**," and the Outside Directors and the Outside Audit and Supervisory Board Members are hereinafter collectively referred to as "**Outside Officers**").

2.3.4 GOM

The GOM is a management executive meeting for the purpose of deliberating, reporting, and discussing important matters concerning the business execution of the Kobayashi Pharmaceutical Group and deliberating important matters that should be submitted to the BOD of Kobayashi Pharmaceutical, and at the same time reviewing the liaison and coordination between Kobayashi Pharmaceutical's headquarters and other divisions (Article 2 of the Regulations for GOM).

The GOM is convened by the Representative Director, President and Chief Operating Officer and held four times a month in principle (Article 5 of the Regulations for GOM). It is stipulated in the Regulations for GOM that the prescribed members of the GOM are the Representative Director, President and Chief Operating Officer, senior general managers, etc.,[8] Full-time Audit and Supervisory Board Members, and the persons designated by the convener (Article 4 of the Regulations for GOM).

While it is determined that the Representative Director, President and Chief Operating Officer makes resolutions by giving an approval under the Regulations for GOM, in practical operation, representatives from each division, including relevant persons handling relevant practical business affairs, participate in the meeting, freely point out problems and express their opinions with each other with respect to each agenda, and when all opinions are expressed, the Representative Director, President and Chief

[8] In Kobayashi Pharmaceutical, Senior Executive Director Yamane and executive officers concurrently serve as senior general managers, etc. of headquarters and departments, and in practice, inside directors, executive officers, and Full-time Audit and Supervisory Board Members, excluding Chairman & CEO Kobayashi, are the members of the GOM. The executive officers as of March 22, 2024 are President & COO Kobayashi, Senior Executive Director Yamane, the Senior General Manager of Healthcare Products Headquarters, the Assistant to the Household Products Headquarters (former General Manager of the Household Products Headquarters), the Senior General Manager of the International Business Division, the General Manager of the China Strategy Department of International Business Division, the Assistant to the Sales Headquarters (former General Manager of the Sales Headquarters), the Head of the Sales Management Division, Deputy Senior General Manager of the Sales Headquarters and the General Manager of the East Japan Management Department, the Senior General Manager of the Manufacturing Headquarters, the Head of the Central R&D Laboratory, the Senior General Manager of the Pharmacovigilance & Consumer Relations Division, the Head of the Chief Digital Officer Unit, and the Head of the Chief Financial Officer Unit.

Operating Officer makes a conclusion.

It is also stipulated in the Regulations for GOM that the minutes of the meetings are prepared for the details of the discussions on the matters submitted to the GOM in principle (Article 13 of the Regulations for GOM).

With respect to the Issue, the Senior General Manager of the Pharmacovigilance & Consumer Relations Division, the General Manager of the Pharmacovigilance Department of the Pharmacovigilance Department of Pharmacovigilance & Consumer Relations Division, and the Food Department Head of the Healthcare Products Headquarters took the lead in explaining the details of the matters to be discussed, and individuals who provided explanations and observers of the relevant agendas also participated for each agenda item.

2.4. Overview of Organizations Related to the Issue

The overview of the organizations within Kobayashi Pharmaceutical that are related to the Issue is as follows.

Organization Name	Outline
Pharmacovigilance & Consumer Relations Division	The Pharmacovigilance & Consumer Relations Division is divided into the Pharmacovigilance Department, the Quality Assurance Department, the Customer Relations Office, the Quality Promoter of Advertising and Packaging Expressions and the Regulatory Affairs Department. The Pharmacovigilance & Consumer Relations Division endeavors to improve the quality assurance system, the pharmaceutical management system, and the pharmacovigilance system, and to control and manage the actions of the Customer Relations Office to improve the reliability of Kobayashi Pharmaceutical Group as a whole.
Pharmacovigilance Department	The Pharmacovigilance Department (i) extensively collects information from the Consumer Affairs Agency and other public offices, and Pharmaceuticals and Medical Devices Agency ("**PMDA**"), and information regarding health damage and adverse drug reactions caused by products that are reported to the Customer Relations Office, (ii) evaluates causal relationships, the degree of seriousness, and other matters with respect to such reports, and conducts detailed investigations thereon (if necessary), (iii) evaluates the necessity of taking measures (such as providing information to consumers and prompt reporting to health centers, the Food Labeling Planning Division of the Consumer Affairs Agency, or other administrative organs) and takes measures if necessary, and (iv) takes other measures, such as the internal compiling of information and the revision of documents to be attached to products.
Quality Assurance Department	The Quality Assurance Department prepares and maintains regulations for domestic product development, audits each process (such as auditing for the purpose of avoiding defect during product development, precautionary

Organization Name	Outline
	measures, and auditing of factory systems), and takes measures to respond to non-conformance (such as investigating the background and cause when a quality issue occurs, planning countermeasures therefor, and reporting to management thereon). With respect to the division of duties between the Quality Assurance Department and the Pharmacovigilance Department, the Pharmacovigilance Department is in charge of information and the like regarding health damage and managing data and samples for sales pitches, while the Quality Assurance Department is in charge of handling defective products and legal issues related to development under domestic laws and regulations, including the Food Sanitation Act.
Customer Relations Office	The Customer Relations Office communicates to the Pharmacovigilance Department any health damage information reported to the Customer Relations Office from medical personnel, distributors, and general consumers as well as any health damage information from the Consumer Affairs Agency and other public offices, and PMDA, and prepares and updates such information in the information management system ("FastHelp") so that it may respond to the reported health damage information and report it internally.
Healthcare Products Headquarters	The Healthcare Products Headquarters is divided into the Medicine Department, the Food Department, the Oral Care Department and the Beauty Care Products Department. Further, each department is divided into the Marketing Group and the R&D Group. In addition to the Departments described above, the Healthcare Products Headquarters has the Direct Marketing Division, the New Market Development Department and the Quality Management Department which it operates in parallel with the Departments described above.
Food Department	The Marketing Group within the Food Department engages in the operations related to the overall product business, brand management, the introduction of new products, product development and planning, and quality labelling. The R&D Group within the Food Department engages in product development operations, and also collaborates with the Central R&D Laboratory to develop products using food materials discovered in the course of the fundamental research at the Central R&D Laboratory. The Food Department also acquires and submits safety data regarding Foods with Function Claims.
Direct Marketing Division	The Direct Marketing Division is divided into the Direct Marketing Department, the Brand Management Group, the Product Planning and Development Group, and the Direct Marketing R&D Group.
Direct Marketing Department	The Direct Marketing Department engages in, with respect to the direct marketing of health care products of Kobayashi Pharmaceutical, the operations related to responses to customers and personal information auditing, operations related to the operational management, operations related to the management of, instructions to, and negotiations with, contractors, and operations related to stores.
Central R&D Laboratory	The Central R&D Laboratory is divided into the Laboratory Assistant

Organization Name	Outline
	Department (Department Attached to the Director), the Foundational Research Department, the OTC Development & Regulatory Department, the New Product and Business Development Department, the R&D Planning and Administration Department, and the Technology Exploration Group.
New Product and Business Development Department	The New Product and Business Development Department consists of three groups: (i) the Pharmacology Research Group, (ii) the Exploratory Clinical Group, and (iii) the R&D Group (of which, the R&D Group is in charge of red yeast rice), and is in charge of the clinical and pharmacological mechanisms that are necessary for the development of Foods with Function Claims.
Manufacturing Headquarters	The Manufacturing Headquarters is divided into the Manufacturing Project Planning Department, the SCM (Supply Chain Management) Department, the Development and Procurement Division (under which there are the Procurement Department, the Quality Management Department, the Healthcare and Household Products Technology Development Department, and the Manufacturing Technology Development Department), the China Manufacturing Strategy Department, the US Manufacturing Strategy Department, the Opening Office for Southeast Asia Strategic Plant, and the Factory Supervision Department (under which there are the Production Engineering Department, and the Factory Elements Technology Promotion Group), and administers the manufacturing subsidiaries (7 domestic subsidiaries and 4 overseas subsidiaries) and a logistics company.
Procurement Department	The Procurement Department selects domestic and foreign manufacturers, orders and manages OEM manufactured products, examines ingredients for use and purchases ingredients, and conducts other operations.
Quality Management Department	The Quality Management Department engages in quality policy management operations (such as operations regarding factory auditing, quality accident auditing (confirmation on effectiveness of permanent measures), urgent and permanent measures upon the occurrence of an issue, shipping decisions and shipment acceptance inspection operations), operations related to quality technology fundamentals (such as quality investigation operations), and manufacturing quality control operations (such as operations for preparing, storing, and revising manufacturing quality guidelines).

2.5 Overview of Red Yeast Rice Related Business

2.5.1 Commencement and Expansion of Sales of Red Yeast Rice Related Business

In June 2016, Kobayashi Pharmaceutical accepted a transfer of a red yeast rice related business, including the red yeast rice production line, from GUNZE LIMITED ("**Gunze**"). For its red yeast rice business, Gunze conducted only manufacturing and selling of red

yeast rice ingredients as Business to Business ("**B-to-B**" or "**B-to-B Business**"). However, Kobayashi Pharmaceutical expanded such business to a Business to Consumer business ("**B-to-C Business**" or "**B-to-C**"), and in May 2018, Kobayashi Pharmaceutical commenced sales of "Beni-koji Choletol," the predecessor of the Products. On June 29, 2020, Kobayashi Pharmaceutical submitted notification of the Products as Foods with Function Claims, and commenced sales of the Products as Foods with Function Claims from April 2021.

The sales of the red yeast rice related business by Kobayashi Pharmaceutical are as follows.

(yen)

Fiscal Year	FY 2021 (104th Term)	FY 2022 (105th Term)	FY 2023 (106th Term)
B-to-C Business	226,014,000	487,913,000	635,940,000
B-to-B Business	125,688,000	126,470,000	135,134,000
Total	351,702,000	614,383,000	771,074,000

As described above, sales of the red yeast rice related business were growing steadily particularly in the B-to-C Business. Kobayashi Pharmaceutical's consolidated annual sales for the fiscal year ended December 2023 were approximately 173 billion yen. Sales of the entire red yeast rice related business comprised approximately 0.44% of the annual sales. Sales of the B-to-C red yeast rice related business that were 635.94 million yen accounted for approximately 3.75% of the sales of the B-to-C Business called Food Department in the Healthcare Products Headquarters that were approximately 16 billion yen. In addition, due to the delay in the plan to submit a notification for Foods with Functional Claims while the expected sales at the time of the business transfer that was 1,050 million yen for the 103rd term (the fifth year from the business transfer) were not achieved in the 106th term, the sales were on an upward trend to meet the sales forecast for the 110th term (12th year from the business transfer) that is 1,450 million yen. The trends in the advertising costs spent by Kobayashi Pharmaceutical for the Products and the ratio thereof to Kobayashi Pharmaceutical 's entire advertising costs of the entire food business are as follows, which indicates Kobayashi Pharmaceutical's attitudes towards expecting the potential of the Products in the food business. (In the following table, the advertising costs for the 105th Term and 106th Term are stated with the figure for the 104th Term being set as "100.")

Fiscal Year	FY 2021 (104th Term)	FY 2022 (105th Term)	FY 2023 (106th Term)
Advertising costs for the Products	100	127	136
Ratio to advertising costs of the food business	Approximately 8.7%	Approximately 12.2%	Approximately 15.0%

The manufacturing of red yeast rice was commenced by moving the manufacturing facilities Kobayashi Pharmaceutical acquired from Gunze to the Osaka Plant (located in Osaka City; the "**Osaka Plant**") and taking in key production and quality control personnel. The number of tanks for cultivating red yeast rice transferred from Gunze upon the business transfer was 16, and as the sales of Kobayashi Pharmaceutical increased, the number of such tanks was subsequently increased to 19 before the closure of the Osaka Plant[9] on December 31, 2023. Then, the number of tanks for cultivating red yeast rice further increased to 24 (including 2 backup tanks) by relocating the manufacturing lines of the red yeast rice to the Kinokawa Plant (located in Kinokawa-shi, Wakayama; the "**Kinokawa Plant**") of Meitanhompo Co., Ltd. ("**Meitanhompo**"), which was separately acquired by Kobayashi Pharmaceutical, and Kobayashi Pharmaceutical increased its production capacity accordingly.

2.5.2 Manufacturing Process of the Products

The Products belonging to the B-to-C Business were manufactured in the following process.

First, sterilized rice and rice germ, and cultivated Monascus fungus are added to water and fermented in tanks for cultivating red yeast rice for a certain period of time at the Osaka Plant (currently the Kinokawa Plant). Once fermentation is complete, the culture in the tanks for cultivating red yeast rice is dried, sterilized, re-dried and crushed. Culture manufactured in this way in one culture tank is referred to as a "culture lot."

Then, at the Osaka Plant, several culture lots are blended to make the total of those lots into specific quantities mainly in order to homogenize the amount of valuable ingredient. The culture lots so blended, after removing foreign substances, conducting X-ray inspection and being sterilized, become the red yeast rice ingredients used for manufacturing the Products. Each specific quantity of the blended red yeast rice ingredients is referred to as an "ingredient lot."

[9] The closure of the Osaka Plant was announced in the Kobayashi Pharmaceutical's press release in November 2022 (Closure of Manufacturing Base/News Release/Kobayashi Pharmaceutical Co., Ltd. (kobayashi.co.jp)).

The Osaka Plant supplied the red yeast rice ingredients it manufactured to its outsourcing company, and the said outsourcing company performed the contracted work of forming and sealing tablets of the Products on an OEM basis. Each lot of the Products manufactured on an OEM basis at the said outsourcing company is referred to as a "product lot."

2.5.3 Known Health Risks of Red Yeast Rice Related Products

It is known that a type of Monascus fungus produces citrinin, which is a mycotoxin, and that citrinin may cause health damage resulting from kidney toxicity to the human body. In this regard, Kobayashi Pharmaceutical conducted a genome analysis of the Monascus fungus used by Kobayashi Pharmaceutical and confirmed that citrinin could not be produced at the genetic level, thus ensuring safety relating to citrinin. While Kobayashi Pharmaceutical had been checking whether citrinin is contained in its red yeast rice ingredients during shipment inspections for B-to-B exports to Taiwan due to overseas laws and regulations, Kobayashi Pharmaceutical had not been checking whether citrinin is contained in its red yeast rice ingredients during shipment inspections for domestic operations where such regulations do not exist. Instead, Kobayashi Pharmaceutical had been confirming whether citrinin is contained in its red yeast rice ingredients once a year as part of its regular inspections for known mycotoxins.[10]

In addition, red yeast rice is produced by fermenting rice with Monascus fungus, and the valuable ingredient called "monacolin K" is obtained through this fermentation process. It is said that this is the same ingredient prescribed as lovastatin, which is approved outside Japan as a prescription pharmaceutical product, and has the effect of lowering cholesterol levels. Rhabdomyolysis has been reported as a known adverse drug reaction of lovastatin and there are indications to this effect in the package inserts of such pharmaceutical products. According to the "Manual for Serious Adverse Drug Reactions: Rhabdomyolysis" (November 2006 edition) published by the Ministry of Health, Labour and Welfare, rhabdomyolysis may complicate acute kidney failure as a result of burdens on the kidney tubules caused by large amounts of muscle components (myoglobin) that leak into the bloodstream. However, since the amount of lovastatin contained in a pharmaceutical product and the ingestion amount each time or per day may differ from the amount of monacolin K contained in the Products and the ingestion amount of the Products each time or per day, it is considered that the indication regarding adverse drug reactions for lovastatin stated in the package inserts does not automatically apply to the

[10] It is said that citrinin has not been detected in the past regular inspections.

Products as well.

The Ministry of Health, Labour and Welfare still continues to determine the possible causative substance of the Issue in cooperation with the National Institute of Health Sciences and the Osaka Institute of Public Health. As of May 31, 2024, it was announced that (i) in addition to puberulic acid, the ingredient lots for the Products contain Compound Y ($C_{28}H_{42}O_8$) and Compound Z ($C_{23}H_{34}O_7$), which are presumed to have a similar molecular structure to monacolin K but are not known natural compounds, (ii) that kidney toxicity was confirmed in animal testing using rats, and with respect to both puberulic acid alone and the Products containing puberulic acid, Compound Y and Compound Z, degeneration or necrosis of the proximal tubules of rats were observed and kidney problems were confirmed, and (iii) the degree of contribution by Compound Y and Compound Z is still under investigation.[11] It was also announced that they continue to examine whether there was a causal relationship between the Products and individual health damage.

[11] See "Future Measures for System for Foods with Function Claims as a Result of the Case Relating to the Red Yeast Rice Related Products" announced by the Ministry of Health, Labour and Welfare on May 31, 2024, and "Measures for Cases Relating to Foods including Red Yeast Manufactured by Kobayashi Pharmaceutical" announced by the National Institute of Health Sciences on May 28, 2024. The Ministry of Health, Labour and Welfare is continuing to investigate the cause even after the date of this report.

3 Factual Background up to the Press Release

The actions of Kobayashi Pharmaceutical officials are summarized below in chronological order from Monday, January 15, when Kobayashi Pharmaceutical was first informed of a case of kidney problems that occurred after ingestion of the Product, to Friday, March 22, the date of the Press Release.

3.1 Six Case Reports Since Mid-January 2024 and Past Inquiries

Kobayashi Pharmaceutical was informed of kidney problems that occurred after ingestion of the Product, and reported those cases successively at GOMs held between Tuesday, February 13 and Tuesday, March 19[12] (hereinafter collectively referred to as the "**Cases**"). A summary of each Case is provided in **Attachment 3.1**, numbered in order from the earliest to the latest case reported to GOM. In this report, each Case is referred to as "Case 1," etc., using the number assigned in **Attachment 3.1**.

The Customer Relations Office of the Pharmacovigilance & Consumer Relations Division ("**Customer Relations Office**") received a total of six contacts concerning Cases 1 to 6, which were the first six Cases, during the half-month period from between Monday, January 15[13][14] to Thursday, February 1. Outlines thereof are as follows, concerning patients in their 40s to 70s (five female patients and one male patient).

Details of initial contacts

Case	Date of Contact	Person who Contacted	Summary of Initial Contact Regarding the Case
Case 1	January 15	A medical doctor	・ The patient, who had ingested the Product, had acute kidney failure and was hospitalized and undergoing dialysis treatment.
Case 2	January 31	A consumer	・ A medical doctor diagnosed that the patient had abnormalities in the patient's kidney tubes and other areas, and there is a possibility that the cause was the Product.
Case 3	February 1	A medical doctor	
Case 4			

[12] On this date, the last GOM prior to Friday, March 22, which is the date of the Press Release, was held.
[13] Hereinafter, all dates in this section mean those in 2024 unless otherwise noted.
[14] Hereinafter, the report will focus on the facts during the two-month period from mid-January to late March 2024. Since the day of the week can also be an important factor in the two-month time frame, the following fact-findings include the day of the week for each date.

Case	Date of Contact	Person who Contacted	Summary of Initial Contact Regarding the Case
Case 5			・ In these three cases of tubulointerstitial nephritis, [15] all of the patients had ingested the Product.
Case 6	February 1	A consumer	・ The patient developed symptoms of creatinine level elevation, and a medical doctor indicated that it may be tubulointerstitial nephritis, [16] and the patient was scheduled to be hospitalized for two months.

Among these, a total of four cases (Case 1, Cases 3 to 5) were reported by medical doctors, and the contents of these cases were similar in that they all involved kidney problems, and were highly specific.

The Customer Relations Office also has the function of receiving information from consumers, medical institutions, retailers, etc. on all products offered by Kobayashi Pharmaceutical,[17] not only health food products. The total number of communications pertaining to all products and the total number of communications pertaining to food and health food products[18] for the period from 2021 to 2023 are shown in the table below. The "complaints" and "inquiries" are broad categories of the content of the communications made within the Customer Relations Office. Generally, "complaints" refers to communications that include a certain level of specific comments related to quality or health aspects of products, for which customers, etc., hold dissatisfaction, etc., while "inquiries" refers to general questions, communications, etc., other than "complaints." The number of "complaints" concerning health aspects is the number shown in the "physical-related" row in the table below.

[15] According to "Manual for Serious Adverse Drug Reactions: Interstitial nephritis (Tubulointerstitial Nephritis) (June 2007 edition (revised in June 2018))" of the Ministry of Health, Labour and Welfare, tubulointerstitial nephritis is a disease that causes inflammation of the renal tubules and surrounding tissue (interstitium), and patients may experience fever and rash due to a systemic allergic reaction, as well as lateral abdominal pain and lower back tension due to swelling of the kidneys. This disease is considered most commonly to occur after taking antibacterial medications, peptic ulcer medications, antituberculosis medications, antipyretic analgesics, antiepileptic medications, and gout medications, and allergic reactions to these medications are thought to be the cause.

[16] During the contact, the term "interstitial nephritis" appears to have been used, but as indicated in footnote 15, this is understood to be the same as "tubulointerstitial nephritis," and therefore the term "tubulointerstitial nephritis" is used throughout in this report.

[17] Product categories include food and health food products, as well as pharmaceutical products, oral care, pocket warmers, skin care, foot care, hygienic goods, household goods, household detergents, deodorants, air fresheners, toilet cleaning agents, and other miscellaneous categories.

[18] Food and health food products pertaining to physical related complaints include supplements other than the Products, tea, and confectioneries.

	2021	2022	2023	Total
Total number of communications pertaining to all products	86,841	76,621	70,907	234,369
Complaints	28,537	26,743	26,210	81,490
Inquiries	58,304	49,878	44,697	152,879
Total number of communications pertaining to food and health food products	7,954	6,544	5,967	20,465
Complaints	1,692	1,419	1,320	4,431
Physical-related	501	528	454	1,483
Inquiries	6,262	5,125	4,637	16,024

Among all products offered by Kobayashi Pharmaceutical, the total number of "complaints" and "inquiries" from medical institutions to the Customer Relations Office from 2021 to 2023 is shown in the table below.

	2021	2022	2023	Total
Pharmaceutical products	33	29	33	95
Complaints	10	9	10	29
Inquiries	23	20	23	66
Food/Health food products	24	20	10	54
Complaints	2	2	2	6
Inquiries	22	18	8	48
Others	270	209	161	640
Complaints	67	73	34	174
Inquiries	203	136	127	466
Total	327	258	204	789

As shown above, the number of "complaints" pertaining to food and health food products from medical institutions to the Customer Relations Office was six in three years. Of which, only one case was reported as a case of hospitalization in 2021.[19] As for pharmaceutical products, the number of "complaints" from medical institutions was 29 in three years, of which only two cases in 2021 and two cases in 2023 were reported by medical institutions as cases of hospitalization, and there is no commonality in the products at issue or timing of each case. The number of other "complaints" was 174 in three years.

As such, Kobayashi Pharmaceutical had never in the past received information from medical institutions regarding serious cases as many as four cases in about half a month.

[19] This case was a case report from a medical doctor regarding a suspected case of certain pneumonia related to a specific product.

However, as stated in 4.2.3 below, Kobayashi Pharmaceutical adopted its interpretation that reporting to governmental authorities is required "only when the causal relationship is clear" between the health damage reported in each case and the Product, and believed that reporting to governmental authorities and a product collection should be conducted together, which was the reason why the company did not conduct reporting to governmental authorities or a product collection until Friday, March 22.

3.2 Case 1: First Case Report From a Medical Doctor (Hospital α)

3.2.1 Outline of Case Report Regarding Case 1

On Monday, January 15, the Customer Relations Office of Kobayashi Pharmaceutical was contacted by A, a medical doctor who works at Hospital α, located in the Kyushu Region ("**Medical Doctor A**"), to the effect that a patient who had been ingesting the Product had acute kidney failure and was hospitalized and undergoing dialysis treatment (Case 1).[20]

Upon the above contact, Medical Doctor A (i) inquired as to whether there had been any reports of acute kidney failure related to the Product, (ii) (if there were any reports) requested Kobayashi Pharmaceutical to share the results of internal examination on the Product and acute kidney failure, and (iii) requested Kobayashi Pharmaceutical to share relevant research papers. Medical Doctor A also informed the Customer Relations Office that the patient started ingesting the Product in early December of 2023, and that symptom of acute kidney failure appeared after only about two weeks of ingesting the Product.

The Customer Relations Office had an internal rule to summarize and send the received "complaints" to the relevant departments on the following day, but since Case 1 was reported by a medical doctor and was highly serious, the member of the Customer Relations Office reported to all employees belonging to the Pharmacovigilance Group within the Pharmacovigilance Department ("**Pharmacovigilance Group**") on the same day of Monday, January 15. For reasons such as that the content of the inquiry from Medical Doctor A was not something that could be handled at the Customer Relations Office, the member of the Pharmacovigilance Group who received the report was tasked

[20] The Customer Relations Office also received a report from a consumer on Thursday, January 11, that their kidney and creatinine levels were high, and that they have had heartburn and their creatinine numbers have gotten worse. However, in this case, the specific values were unclear, and a medical doctor had prescribed gastrointestinal and cholesterol-lowering medications, with no direct treatment for kidneys. Therefore, the member of the Pharmacovigilance Department determined that the correlation between this case and the Product was unclear.

with answering questions and recording correspondence with Medical Doctor A on behalf of the member of the Customer Relations Office. The member of the Pharmacovigilance Group, upon consulting with the head of the Pharmacovigilance Group, started handling the situation.

The member of the Pharmacovigilance Group and Medical Doctor A continued to communicate with each other by telephone and email thereafter. On Wednesday, January 17, in response to a contact from Medical Doctor A, as an answer to Medical Doctor A's inquiry (i) above, the member of the Pharmacovigilance Group reported that there were no cases of acute kidney failure with causal relationship to the Product that Kobayashi Pharmaceutical was aware of. During this contact, Medical Doctor A provided the member of the Pharmacovigilance Group with the information that the Product was the only plausible factor with a temporal association to acute kidney failure, and the patient had no concomitant medications or medical history. When Medical Doctor A contacted the member of the Pharmacovigilance Group on Thursday, January 18, Medical Doctor A also inquired as to whether the Product contained citrinin, to which the member of the Pharmacovigilance Group responded on Monday, January 22, that Kobayashi Pharmaceutical had not been using a strain of bacteria that produces citrinin in the manufacture of the Product. In addition, as an answer to Medical Doctor A's inquiry (iii) above, the member of the Pharmacovigilance Group informed that, upon a literature search conducted using online research databases, no information related to kidney failure was found regarding red yeast rice, the main ingredient of the Product.[21] On Friday, February 2, Medical Doctor A informed Kobayashi Pharmaceutical that the kidney failure in Case 1 was due to tubulointerstitial nephritis, and on Thursday, February 8, Medical Doctor A provided Kobayashi Pharmaceutical with a photograph showing that the product lot number of the Product ingested by the patient in Case 1 was H3017. On the other hand, Kobayashi Pharmaceutical did not confirm with Medical Doctor A until Thursday, February 29, when the interview with Medical Doctor A was conducted, as to whether Case 1 was a symptom of rhabdomyolysis attributable to monacolin K.

3.2.2 Status of Discussion on Case 1 Within the Pharmacovigilance Department

On Friday, January 19, a meeting was held among the Pharmacovigilance Department

[21] On Friday, January 26, Medical Doctor A requested the member of the Pharmacovigilance Group to conduct research on acute kidney failure attributable to equol, because the patient had been ingesting equol manufactured and distributed by Kobayashi Pharmaceutical. In response to this request, on Friday, February 2, the member of the Pharmacovigilance Group reported to Medical Doctor A to the effect that no relevant information was found as a result of research.

Manager, the Pharmacovigilance Group Manager, and the member of Pharmacovigilance Group with regard to Case 1. At the meeting, information that the member of the Pharmacovigilance Group had collected by that time and documents organizing the content of communication with Medical Doctor A were shared by the member of the Pharmacovigilance Group with the Pharmacovigilance Department Manager, and the attendees discussed the response going forward. Based on the result of the discussion, the member of the Pharmacovigilance Group responded to the inquiry from Medical Doctor A on Wednesday, January 17 as described in 3.2.1 above.

However, the Pharmacovigilance Department Manager did not report Case 1 to the Senior General Manager of Pharmacovigilance & Consumer Relations Division at that time. The reason was that, the member of the Pharmacovigilance Group had received an explanation from Medical Doctor A that the causal relationship between the Product and kidney problems was unclear, and the internal regulations for pharmaceutical products stipulate that, it shall be reported to the General Manager of the Pharmacovigilance & Consumer Relations Division when there are four unknown serious cases that are not listed on the package insert, and the member of the Pharmacovigilance Group had referred to these internal regulations.[22]

3.3 Cases 3 to 5: Three Case Reports Provided Simultaneously by a Medical Doctor (Hospital β)

3.3.1 Outline of the Reports on Cases 3 to 5

On Thursday, February 1, about half a month after being contacted about Case 1, Kobayashi Pharmaceutical received a report from a medical doctor of three cases of tubulointerstitial nephritis, a type of acute kidney failure, that had occurred at a single medical institution.

That is to say, on Thursday, February 1, the Customer Relations Office was contacted by B, a medical doctor who works at Hospital β located in the Kanto Region ("**Medical Doctor B**"), about three cases of tubulointerstitial nephritis (Cases 3 to 5). All of these three patients had ingested the Product.

When contacting about these cases, Medical Doctor B inquired the member of the Customer Relations Office whether the Product contained citrinin, as did Medical Doctor A in Case 1, and inquired whether there had been any reports of tubulointerstitial nephritis

[22] The internal regulations did not provide for such specific reporting criteria similar to pharmaceutical products for food products.

due to ingestion of the Product. The member of Customer Relations Office responded to Medical Doctor B that the Product was shipped after confirming that citrinin was not detected in multiple lots of the Product. On that occasion, the member of Customer Relations Office responded to the effect that there had been no report of tubulointerstitial nephritis without mentioning the fact that Medical Doctor A had already reported acute kidney failure in Case 1 in relation to the Product.

In addition, Medical Doctor B pointed out to the member of the Customer Relations Office that tubulointerstitial nephritis is a unique case of kidney failure with only three to four cases per year at Hospital β, and despite that, three cases had occurred in the last one to two months, and all of the three patients had ingested the Product. Based on these facts, Medical Doctor B stated that, although the causal relationship with the Product was unclear, Medical Doctor B would like Kobayashi Pharmaceutical to alert consumers to be aware of the possibility of developing tubulointerstitial nephritis, since there had been cases of users of the Product developing tubulointerstitial nephritis.[23]

3.3.2 Internal Response, Etc. After the Reports of Cases 3 to 5

On Thursday, February 1, the member of the Customer Relations Office reported Cases 3 to 5 to the Pharmacovigilance Department. In light of the fact that multiple cases had occurred in a short period of time, the Pharmacovigilance Department Manager emailed the Senior General Manager of Pharmacovigilance & Consumer Relations Division to share information regarding Cases 3 to 5 on the evening of the same day. On that occasion, it was also shared that reporting to governmental authorities was not necessary at that time because the causal relationship was unknown.

In response to the above sharing of information by the Pharmacovigilance Department Manager, on Friday, February 2, the Pharmacovigilance & Consumer Relations Division, led by the Quality Assurance Department of the Pharmacovigilance & Consumer Relations Division ("**Quality Assurance Department**"), confirmed whether any problematic results had been detected in past inspections under the Food Sanitation Act (fungal toxins, aflatoxins, allergens, radiation, etc.), which were conducted annually on all health food products, and reviewed if there had been any changes in the ingredients or formulation of the Products. On the same day, the Pharmacovigilance Group Manager emailed relevant persons regarding the Products in the Healthcare Products Headquarters and the Pharmacovigilance & Consumer Relations Division, to share that there had been

[23] Consequently, Kobayashi Pharmaceutical did not issue any alert to the users of the Products until Friday, March 22, when the company issued the Press Release.

reports of Case 1 and Cases 3 to 5 from medical doctors.

On Friday, February 2, the member of the Pharmacovigilance Group obtained approval from Medical Doctor A and Medical Doctor B to conduct a detailed investigation.[24]

3.3.3 Reports of Other Cases of Kidney Problems

On Wednesday, January 31, the Direct Marketing Department of the Direct Marketing Division of the Healthcare Products Headquarters (hereinafter, the Division is referred to as "**Direct Marketing Division**," and the Department is referred to as "**Direct Marketing Department**") was contacted by a consumer who had purchased the Product by mail order and ingested the Product. The consumer stated to the effect that it was diagnosed by a medical doctor that the consumer had an abnormality in the consumer's kidney tubes, etc., and that there was a possibility that the Product was the cause (Case 2). However, no further action was taken until the Press Release on Friday, March 22, because the consumer expressed to the Direct Marketing Department at that time that such consumer did not need to be contacted by Kobayashi Pharmaceutical. On Thursday, February 1, the Direct Marketing Department reported Case 2 to the member of the Pharmacovigilance Group, and the member of the Pharmacovigilance Group shared the relevant information with the Pharmacovigilance Department Manager and the Pharmacovigilance Group Manager.

In addition, on Thursday, February 1, the Direct Marketing Department was contacted by another consumer who had used the Product, to the effect that the consumer had experienced a symptom of elevated creatinine, to which a medical doctor had indicated the possibility of tubulointerstitial nephritis, and that the consumer was going to be hospitalized for two months (Case 6). However, there is no evidence that any particular action was taken on Case 6 by Kobayashi Pharmaceutical until Monday, February 26.

Compared to Cases 3 to 5, in which multiple similar cases were reported in a short period of time, the Pharmacovigilance & Consumer Relations Division did not give priority to Case 2 and Case 6 because the amount of information was insufficient since they were both reported by consumers who ingested the Product, and were not directly provided by medical doctors.

[24] Detailed investigation on a medical doctor means, when there is a patient who has developed health damage after ingesting a product, interviewing the doctor in charge to obtain details of the patient's medical condition and the medical doctor's opinion on the causal relationship to the product in question. Typical ways are that medical doctors are asked in advance to write down the patient's medical condition, the pharmaceutical products and supplements the patient was ingesting, and the medical doctor's opinion in a document called a "Detailed Questionnaire," and the medical doctor is interviewed based on the Detailed Questionnaire.

3.4 Initial Response by the Pharmacovigilance & Consumer Relations Division

3.4.1 Ad-hoc Meeting at the Pharmacovigilance & Consumer Relations Division

Following the report of Cases 1 to 6, the Pharmacovigilance & Consumer Relations Division held an ad-hoc meeting with persons concerned from various departments within the Pharmacovigilance & Consumer Relations Division at 12:00 p.m. on Monday, February 5 ("**Feb. 5 Ad-hoc Meeting**").[25][26] On Friday, February 2, the Pharmacovigilance Group Manager announced that the Feb. 5 Ad-hoc Meeting would be held, and in addition to the member of the Pharmacovigilance Department, the Senior General Manager of Pharmacovigilance & Consumer Relations Division, the General Manager of the Quality Assurance Department of the Pharmacovigilance & Consumer Relations Division, the Manager of the Quality Assurance Group (Japan) of the Quality Assurance Department, and other persons concerned also attended the Feb. 5 Ad-hoc Meeting.

At the Feb. 5 Ad-hoc Meeting, the member of the Pharmacovigilance Department reported on Cases 1 to 6, and the attendees discussed risk analysis and cause analysis of the Products, among other matters.

During the meeting, three hypotheses were formulated as the possible causes of the Cases: (i) the possibility that it was due to citrinin, (ii) the possibility that people who react to statins, including monacolin K, which is the valuable ingredient of the Product, happened to ingest the Product, and (iii) the possibility that other substances affected or contaminated. It was decided that a cause analysis would be conducted moving forward.

As a result of the Feb. 5 Ad-hoc Meeting, it was decided that the New Product and Business Development Department of the Central R&D Laboratory ("**New Product and Business Development Department**"), the Food R&D Group of the Food Department ("**Food R&D Group**"), the Quality Assurance Department, and the Pharmacovigilance Department would each take the following actions to address the respective hypotheses.

Department in charge	Content of response
New Product and Business	Confirming safety data on citrinin and monacolin K, citrinin testing (meaning testing as to whether each lot, etc. contains citrinin; the same shall apply

[25] Since then, several meetings and interviews with external experts (medical doctors and attorneys) have been held within Kobayashi Pharmaceutical to discuss the response on the Products. Although there is a mix of offline and online participants in these meetings and interviews, they are described without any particular distinction in this report.

[26] According to the Pharmacovigilance & Consumer Relations Division, such ad hoc meetings are held once a year or so.

Department in charge	Content of response
Development Department and Food R&D Group	hereinafter) of all lots (products, raw ingredients, and culture lots that can be confirmed and tested) including past testing, and confirming impact on other products
Quality Assurance Department	Confirming safety data (changes in the product, etc.) at the time of manufacture
Pharmacovigilance Department	Compiling data on adverse reactions and coordinating detailed investigation on medical doctors

Although, as described in 3.3.1 above, Medical Doctor B of Hospital β, the doctor in charge of Cases 3 to 5, stated that Medical Doctor B would like Kobayashi Pharmaceutical to alert consumers regarding the correlation between the Product and kidney problems, there is no indication that any particular discussion took place at the Feb. 5 Ad-hoc Meeting as to whether to alert consumers. There is also no indication that any discussion took place at the Feb. 5 Ad-hoc Meeting to accelerate the schedule for the detailed investigation on medical doctors.

3.4.2 Report at Monthly Meeting Between President & COO Kobayashi and the Pharmacovigilance & Consumer Relations Division on February 6

Following the Feb. 5 Ad-hoc Meeting, the Senior General Manager of the Pharmacovigilance & Consumer Relations Division reported the Issue to President & COO Kobayashi at the monthly meeting between the Pharmacovigilance & Consumer Relations Division and President & COO Kobayashi held on Tuesday, February 6 ("**Feb. 6 Monthly Meeting**").[27]

At the Feb. 6 Monthly Meeting, the Senior General Manager of the Pharmacovigilance & Consumer Relations Division reported on hospitalizations, cause analysis (presentation of hypotheses), and the response going forward, among other matters using materials prepared for the Feb. 5 Ad-hoc Meeting. As a result, it was decided to proceed with investigations such as the detailed investigation on medical doctors and product lot testing, and to report on the progress of investigations on Cases 1 to 6 at the regular GOM on Tuesday, February 13 ("**Feb. 13 GOM**"). In other words, at the Feb. 6 Monthly Meeting, the Pharmacovigilance & Consumer Relations Division reported that the three hypotheses described in 3.4.1 above ((i) the citrinin hypothesis, (ii) the monacolin K hypothesis, and (iii) the contamination hypothesis) were possible, and that each department would

[27] Monthly meetings are held once a month to provide President & COO Kobayashi with a report on the current month's status and other matters from the Manager of the Customer Relations Office and the General Manager of the Quality Assurance Department.

proceed with cause analysis, etc., which was approved by President & COO Kobayashi.

3.4.3 Response After Feb. 5 Ad-hoc Meeting and Feb. 6 Monthly Meeting

Following the Feb. 5 Ad-hoc Meeting and the Feb. 6 Monthly Meeting, the New Product and Business Development Department and the Food R&D Group conducted a literature search regarding citrinin and monacolin K and kidney problems. The specific subject of the literature search included materials pertaining to the safety of the Products at the time of notification as Foods with Function Claims, the correlation between citrinin and monacolin K (and lovastatin, which is the same constituent) and kidney problems, and the correlation between the duration of ingesting citrinin and monacolin K (and lovastatin, which is the same constituent) and adverse effects, among other matters.

As stated in 2.5.3 above, red yeast rice ingredients used in the domestic business were not subject to citrinin inspection for shipping inspections. As stated in 3.5.2 below, citrinin inspection was decided to be conducted for ingredient lots and product lots, and on Wednesday, February 7, the member of the Food R&D Group commissioned an outside contractor to conduct the investigation.

In addition, the Quality Assurance Department, following the Feb. 5 Ad-hoc Meeting, on the same day, requested the member of the Quality Management Group of Meitanhompo[28] to confirm whether there had been any changes in the rice and rice germ that are used in red yeast ingredients used for the Products, and in the manufacturing process for red yeast ingredients, in 2023, in order to investigate the possibility of contamination. This request for confirmation regarding changes in the manufacturing process concerned changes in manufacturing conditions and changes in personnel, and did not include whether or not there had been any incidents such as equipment breakdowns. According to the information obtained from the member of the Quality Management Group of Meitanhompo, no particular changes were found. At the same time, it was confirmed with the outsourcing company that had conducted the OEM production of the Products whether there was any changes in ingredients, but no particular changes were found, either. Based on the results of this brief confirmation, the Pharmacovigilance & Consumer Relations Division concluded that the possibility of contamination during the manufacturing process for individual lots was low, and did not give priority consideration to such possibility. Subsequently, investigations for some toxic substances

[28] As described in 2.5.1 above, the Osaka Plant was closed in December 2023, and the production lines including the manufacturing facilities for the Products and the manufacturing and quality control personnel were transferred, etc. to the Kinokawa Plant from January 2024. Therefore, it was necessary to confirm with employees of Meitanhompo as to the changes at the Osaka Plant in 2023.

were conducted as described in 3.7.1 below, although, discovery of the presence of unanticipated constituents contained in individual lots failed until when Peak X was discovered in mid-March as described in 3.9 below.

As stated in 3.3.1 above, Medical Doctor B had stated that Medical Doctor B would like Kobayashi Pharmaceutical to alert consumers regarding the correlation between the Product and kidney problems. Although this was discussed within the Pharmacovigilance & Consumer Relations Division, no immediate alert was made based on the idea that the response to be taken would depend on the cause.

With regard to the detailed investigation on medical doctors, detailed investigations with both medical doctors were scheduled to be conducted between February 19 and 29. Some stated that the reason for this timing was that Kobayashi Pharmaceutical took the equivalent action in relation to the Products, Foods with Function Claims, as it does when information is provided by a medical institution regarding a known side effect of a pharmaceutical product manufactured and distributed by Kobayashi Pharmaceutical.

3.5 Status of Initial Discussions at the GOM

3.5.1 Discussions at the Feb. 13 GOM

On Tuesday, February 13, the Feb. 13 GOM was held. For many of the GOM participants, the Feb. 13 GOM was where they first became aware of the Issue. Senior Executive Director Yamane, Full-time Audit and Supervisory Board Member Yamawaki, and Full-time Audit and Supervisory Board Member Kawanishi also first became aware of the Issue at the Feb. 13 GOM.

In addition, at the Feb. 13 GOM, discussions were held primarily on the hypotheses for the Issue. Specifically, prior to the Feb.13 GOM, there were the three hypotheses described in 3.4.1 above ((i) the citrinin hypothesis, (ii) the monacolin K hypothesis, and (iii) the contamination hypothesis). However, as of the time of the Feb. 13 GOM, as stated in 3.4.3 above, the possibility of contamination had been excluded from priority consideration because, as a result of having confirmed in a brief manner whether there were any changes in manufacturing methods, etc., no particular changes were found. Therefore, it was decided that verifying the citrinin hypothesis and the monacolin K hypothesis would be given priority. Specifically, the participants confirmed that information would be collected by visiting each medical doctor from Monday, February 19 to Thursday, February 29, and an analysis of the ingredient lots and product lots in

order to confirm the existence of citrinin will be conducted.[29]

Further, at the Feb. 13 GOM it was also confirmed that the plan would be to conduct an evaluation of the Cases and reporting to governmental authorities, if necessary, based on the results of the investigation stated above, and the criteria and internal rules for conducting reporting to governmental authorities for health damage were arranged as backup materials. Said materials stated that reporting to governmental authorities on Foods with Function Claims were required "only when the causal relationship is clear" between a product and the resulting health damage.

In addition, at the Feb. 13 GOM, President & COO Kobayashi believed, and in fact made a statement, to the effect that any response concerning the Issue which disregarded safety would be unacceptable, and that depending on the results of the investigation, there was a possibility of issuing a collection and discontinuing the Product. In addition, Senior Executive Director Yamane pointed out that with respect to the three cases at Hospital β, under ordinary circumstances the probability of three such cases arising simultaneously was low, and therefore the alert level should be raised.

3.5.2 Analysis of the Cause, Etc. Following the Feb. 13 GOM

As a result of the analysis of the lots for citrinin which had been decided at the Feb. 13 GOM to be performed (the analysis targets were set as all ingredient lots from 2021 to 2023 and the product lot (J304) ingested by the patients in some of the Cases), on Friday, February 16, it was found that citrinin had not been detected in the said lots which were subject to the analysis.

In response to these results, the Senior General Manager of the Healthcare Products Headquarters, the Food Department Manager, and the Food R&D Group Manager held a meeting on Friday, February 16 regarding the response plan going forward. At said meeting, the participants discussed to the effect that since citrinin had not been detected, the likelihood of monacolin K being the cause of the Cases was high. Accordingly, the participants discussed that responses such as setting an upper limit of the blending amount for monacolin K and changing the labeling on adverse drug reactions might be necessary.

[29] In addition, participants also discussed "the possibility of allergies to the components contained in the product." Further, with regards to "allergies," while (i) the patients' allergic reactions to foreign substances that had been mixed into the Product and (ii) allergic reactions to the innate components of the Product caused due to the bodily constitution unique to the patients may be considered, at Kobayashi Pharmaceutical, attention was primarily placed on (ii) thereafter, and with regards to (i), attention was barely given from the perspective of contamination focusing on the individual product lot prior to the interview with Medical Doctor A stated in 3.7.4 below, and even after this, sufficient attention was not given until the interview with attorney and medical doctor P stated in 3.8.2 below.

After said meeting ended, the Food R&D Group Manager promptly shared the results of the analysis of the lots for citrinin by email with the Pharmacovigilance Group Manager, members of the Pharmacovigilance Department, members of the Quality Assurance Group (Japan) of the Quality Assurance Department (the "**Domestic Quality Assurance Group**"), etc.

3.5.3 Discussions at the Feb. 20 GOM[30]

On Tuesday, February 20, a regular GOM was held (the "**Feb. 20 GOM**"). At the Feb. 20 GOM, it was reported that, as stated in 3.5.2 above, citrinin had not been detected in the red yeast rice ingredients used in the Product, and as a result, although the specific cause was still unclear, the possibility of citrinin being the cause had become smaller, while it was believed that the likelihood of monacolin K being the cause had become higher.

Therefore, a report was also made on the details of rhabdomyolysis, which could be caused by monacolin K, and the participants considered the necessity of setting an upper limit of the blending amount for monacolin K and changing the labeling on adverse drug reactions, etc. In addition, it was reported that, with regards to the detailed investigations on medical doctors, an interview for Cases 3 to 5 was to be conducted with Medical Doctor B from 4:00 p.m. on Thursday, February 22 at Hospital β, and an interview for Case 1 was to be conducted with Medical Doctor A from 4:00 p.m. on Thursday, February 29 at Hospital α in order to confirm the observations of the medical doctors, patient backgrounds, causal relationship with the Product, and the DLST[31] results. The dates and times for the interviews with each medical doctor were, in case of Hospital β, scheduled to be held three weeks after Kobayashi Pharmaceutical was first contacted therefrom, and in case of Hospital α, scheduled to be held about one and a half months after Kobayashi Pharmaceutical was first contacted therefrom. The backgrounds leading up to the

[30] At the Feb. 20 GOM, based on the proposal by the Senior General Manager of the Pharmacovigilance & Consumer Relations Division, it was decided that no video recordings would be made onwards in order to allow opinions to be freely expressed from various levels of the hierarchy when discussing sensitive matters such as whether or not to take actions such as a collection of the Product, and minutes were also not prepared (there were no particular objections to said proposal.). The GOMs held after the Feb. 20 GOM were handled in the same manner. Therefore, no video recordings nor minutes were made for the GOMs held on or after the Feb. 20 GOM, and there are no remaining objective records regarding the details of the deliberations at said GOMs. As such, the Committee would add that it had no choice but to obtain the details of the deliberations at the GOMs held on or after the Feb. 20 GOM through the materials for each GOM and interviews with the participants.

[31] "DLST" is a test for investigating whether there is a possibility of allergic reactions to pharmaceutical drugs used for medical treatment or other purposes.

interviews are as stated in 3.7.1 and 3.7.4 below. However, it was not confirmed that there were any participants at either the Feb. 13 GOM or the Feb. 20 GOM who pointed out that the schedule for the abovementioned medical doctor interviews was slow.

Thus, the Feb. 20 GOM was focused primarily on reports regarding monacolin K, and therefore the participants at the Feb. 20 GOM did not conduct substantial discussions on reporting to governmental authorities or a product collection.

3.6 Report on the Issue to Chairman & CEO Kobayashi and the Outside Officers

3.6.1 Report to Chairman & CEO Kobayashi

In response to the Feb. 13 GOM, on Wednesday, February 14, the Senior General Manager of the Pharmacovigilance & Consumer Relations Division sent the monthly report for January[32] to Chairman & CEO Kobayashi by email. Said monthly report stated, as risk information, that there had been a series of hospitalizations for kidney problems in patients who had ingested the Product and the details of the deliberations at the Feb.13 GOM regarding the Issue.

Chairman & CEO Kobayashi would usually confirm the monthly reports after his secretary delivered the printed copies of the monthly reports to his house. Therefore, Chairman & CEO Kobayashi confirmed said monthly report on Tuesday, February 20, which was a few days after the printed copy thereof was delivered to his house as always. Afterwards, he sent an email through his secretary to the Senior General Manager of the Pharmacovigilance & Consumer Relations Division, requesting the Senior General Manager of the Pharmacovigilance & Consumer Relations Division to report the details of the Issue. In response, that same day the Senior General Manager of the Pharmacovigilance & Consumer Relations Division reported to Chairman & CEO Kobayashi by email the hypotheses assumed at that point in time and the plan for the investigation going forward, based on the materials presented and the details of the discussions held at the Feb. 20 GOM.[33]

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[32] "Monthly reports" are reports to superiors prepared each month per department by the person in charge in each department which summarize matters such as the performance, challenges, and risk information of the relevant department, and are about the length of a single A4 sheet. These monthly reports are usually prepared by around the early to mid part of the month following the reported month. The monthly reports of each Senior General Manager are submitted to President & COO Kobayashi and Chairman & CEO Kobayashi, as well as to the Full-time Audit and Supervisory Board Members.

[33] Specifically, the Senior General Manager of the Pharmacovigilance & Consumer Relations Division reported to Chairman & CEO Kobayashi on matters such as (i) the fact that the causal relationship between the Product and the Cases was unclear at this point in time and it was believed that an

In reaction to this report, Chairman & CEO Kobayashi, through his secretary, sent a reply to the effect that he had gained a good understanding of the situation, and requested the Senior General Manager of the Pharmacovigilance & Consumer Relations Division to tell the relevant persons in charge to (i) suspend advertising of the Product, (ii) lower the blending amount of monacolin K in the Product, and (iii) proceed with the preparations for a new notification for a product with a reduced blending amount of monacolin K. According to Chairman & CEO Kobayashi, at that stage, reporting to governmental authorities and a collection of the Product were not on his mind.

In response to these instructions, the Senior General Manager of the Pharmacovigilance & Consumer Relations Division shared the abovementioned instructions from Chairman & CEO Kobayashi with the Senior General Manager of the Healthcare Products Headquarters, the Head of the Central R&D Laboratory, the Food Department Head, the Quality Assurance Department Manager, and the Pharmacovigilance Department Manager, and requested them to consider their responses. Further, the Food Department Head, who received these instructions, sent a reply to the Senior General Manager of the Pharmacovigilance & Consumer Relations Division to the effect that with regards to the instructions (i), the Food Department Head believed that advertising could continue if it was determined that there is no causal relationship, and that the Food Department Head was intending to proceed with instructions (ii) and (iii) regardless of the existence or absence of a causal relationship. The Senior General Manager of the Healthcare Products Headquarters also sent a reply to the effect that while continuing advertising, the matter would be discussed following detailed investigations on medical doctors and consultations with experts.

Following the abovementioned exchange, the Head of the Central R&D Laboratory and the Food Department Head reported to Chairman & CEO Kobayashi that with regards to instruction (i), they were considering continuing the advertising and that they were considering proceeding with instructions (ii) and (iii). Chairman & CEO Kobayashi did not object to these responses.

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immediate product collection was unnecessary; (ii) because, as a result of the investigation, citrinin had not been detected in the Product, it was believed that the possibility of citrinin hypothesis being the cause was low; (iii) it was assumed that monacolin K hypothesis was the cause; and (iv) it was believed that the existence or absence of a causal relationship must be confirmed as soon as possible. In addition, the Senior General Manager of the Pharmacovigilance & Consumer Relations Division reported that, for the plan for the response going forward, responses such as the following were being considered: (i) continuing with the collection of information, including conducting the detailed investigations on medical doctors, (ii) proceeding with preparations for attorney consultations regarding the existence or absence of a causal relationship, (iii) changing the labeling regarding monacolin K on the Product and lowering the blending amount of monacolin K in the Product, and (iv) making an application for a new product with a reduced blending amount of monacolin K.

3.6.2 Status of Information Sharing with the Outside Officers

3.6.2.1 Status of Information Sharing with the Outside Directors

As stated in 3.9.4 below, the executives of Kobayashi Pharmaceutical reported the Issue to the Outside Directors on the evening of Wednesday, March 20. However, with regards to this point, on Friday, February 16, the General Manager of the General Affairs Department of the Sustainability Management Headquarters ("**General Affairs Department General Manager**") sent the monthly report for January (this was the version selected by the Full-time Audit and Supervisory Board Members to be materials for an Audit and Supervisory Board meeting pursuant to 3.6.2.2 below.) by email to Outside Director Chiaki Ariizumi ("**Outside Director Ariizumi**") from among the Outside Directors.[34] However, Outside Director Ariizumi did not open the email with said monthly report attached immediately; she first ascertained the details of said monthly report on Thursday, March 21 after reading the abovementioned report sent by email on the evening of Wednesday, March 20. This was because from around the time of the spring of 2023, Outside Director Ariizumi had not been reviewing the extensive monthly reports each time she received them, but instead had been using them to retrospectively confirm any matter that caught her attention during the discussions at the BOD meetings.

3.6.2.2 Status of Information Sharing with the Outside Audit and Supervisory Board Members

Among the Audit and Supervisory Board Members, the Full-time Audit and Supervisory Board Members are GOM members, and therefore became aware of the Issue at the Feb. 13 GOM. On Friday, February 16, Full-time Audit and Supervisory Board Member Yamawaki sent printed copies of a portion of the monthly report[35] for January to

[34] At Kobayashi Pharmaceutical, monthly reports are usually not sent to Outside Directors. However, Outside Director Ariizumi had previously been receiving monthly reports during her term of office as an Outside Audit and Supervisory Board Member of Kobayashi Pharmaceutical. Outside Director Ariizumi believed that monthly reports were useful for ascertaining important information regarding Kobayashi Pharmaceutical, and had been receiving the monthly reports each month by requesting them from the General Affairs Department General Manager.

[35] Among the monthly reports for each month, the Full-time Audit and Supervisory Board Members had been selecting management issues for which reporting and the like to the Outside Audit and Supervisory Board Members was thought to be necessary, and were using such monthly reports as materials for the regular monthly Audit and Supervisory Board meeting. 52 reports are included in

Outside Audit and Supervisory Board Member Hatta and Outside Audit and Supervisory Board Member Moriwaki as materials for the Audit and Supervisory Board meeting scheduled to be held on Wednesday, February 21 (the "**Feb. 21 Audit and Supervisory Board Meeting**").

Outside Audit and Supervisory Board Member Hatta and Outside Audit and Supervisory Board Member Moriwaki first became aware of the Issue at the Feb. 21 Audit and Supervisory Board Meeting, when they received the explanation stated in said portion of the monthly report from the Full-time Audit and Supervisory Board Members.

At the Feb. 21 Audit and Supervisory Board Meeting, the Full-time Audit and Supervisory Board Members explained the overview of the Issue, and questions and answers were exchanged between the Full-time Audit and Supervisory Board Members and the Outside Audit and Supervisory Board Members. The summery regarding the Issue at the Feb. 21 Audit and Supervisory Board Meeting confirmed that the Audit and Supervisory Board needed to pay close attention to the Issue, and due to the nature of the matter, that Kobayashi Pharmaceutical must not be slow to react.

At the Audit and Supervisory Board meeting, around 15 to 20 monthly reports are discussed each month. Usually, the participants spend only about two to three minutes on each monthly report. At the Feb. 21 Audit and Supervisory Board Meeting, the participants spent slightly less than ten minutes all together on the report, including on the product explanation of the Product, and question and answer exchanges regarding the Issue.

3.7 Detailed Investigation on the Doctors in Charge of Case 1 and Cases 3 to 5 and Responses Thereafter

3.7.1. Detailed Investigation on Medical Doctor B of Hospital β

On Thursday, February 15, the person in charge in the Pharmacovigilance Group sent an email to Medical Doctor B of Hospital β, who was the doctor in charge in Cases 3 to 5, requesting Medical Doctor B to have an interview with Kobayashi Pharmaceutical and proposing the period from Tuesday, February 20 to Thursday, February 29 as potential interview dates. In response, during the day on Thursday, February 15, Medical Doctor B replied and an interview between Kobayashi Pharmaceutical and Medical Doctor B was

each monthly report; of these, around 40 reports are selected each month by the Full-time Audit and Supervisory Board Members as materials for the Audit and Supervisory Board meeting. From these approximately 40 reports, around 15 to 20 reports are actually reported on at the Audit and Supervisory Board meeting.

set for Thursday, February 22 (the "**Feb. 22 Medical Doctor Interview**").

From Kobayashi Pharmaceutical, the Pharmacovigilance Department Manager, the Food R&D Group Manager, and other persons concerned participated the Feb. 22 Medical Doctor Interview. They had an interview with Medical Doctor B from 4:00 p.m. to 5:15 p.m. on Thursday, February 22 at Hospital β.

In this Interview, Medical Doctor B stated that the observed symptoms in each of Cases 3 to 5 were not that of kidney problems attributable to rhabdomyolysis as a result of monacolin K, but that the tubulointerstitial nephritis was thought to be caused by allergic reactions to the Product. Medical Doctor B further pointed out that Medical Doctor B had the impression that the tubulointerstitial nephritis in Cases 3 and 4 could have been due to some kind of toxicity, though specifically what kind was unclear.

Next, in terms of the correlation between the Product and each of Cases 3 to 5, while tubulointerstitial nephritis is said to often occur from pharmaceutical drug use, Medical Doctor B stated that from Medical Doctor B's own observations, Medical Doctor B strongly suspected that the cause in Case 5 was the onset of symptoms due to an allergic reaction as the result of the patient's ingesting of the Product, because the results of the DLST were positive and the only pharmaceutical product or dietary supplements the patient had ingested prior to the onset of the symptoms was the Product.[36] In addition, for Case 3, Medical Doctor B considered the possibility of a causal relationship, although it was difficult to specify the cause because the patient had a history of ingesting pharmaceutical products and dietary supplements other than the Product, and for Case 4, Medical Doctor B commented that Medical Doctor B strongly suspected a causal relationship because the only pharmaceutical product or dietary supplement the patient had ingested prior to the onset of symptoms was the Product.[37]

In addition, Medical Doctor B proposed adding a note to the precautions for ingestion for consumers to seek a diagnosis from a medical doctor if symptoms of tubulointerstitial nephritis appeared.

Then, on the evening of Thursday, February 22, the persons from Kobayashi Pharmaceutical in attendance at the Feb. 22 Medical Doctor Interview held an online meeting from a rental meeting room in Tokyo Station with the Senior General Manager of the Healthcare Products Headquarters, the Senior General Manager of the Pharmacovigilance & Consumer Relations Division, the Food Department Head, and

[36] On the detailed interview sheet for Case 5, the checkbox in the "causal relationship" column was marked as "Definite," with the five checkboxes in the "causal relationship" column being "Definite," "Probable," "Possible," "Not related (can be denied)," and "Unknown."

[37] On the detailed interview sheets for both Cases 3 and 4, the checkbox in the "causal relationship" column was marked as "Probable."

other persons concerned, and shared information on the outcome of the Feb. 22 Medical Doctor Interview, including the fact that Medical Doctor B had ruled out rhabdomyolysis as a possible cause.

Thereafter, the Pharmacovigilance Group once again reassessed the situation, including hypotheses other than monacolin K, in order to verify at a GOM whether reporting to governmental authorities for Cases 3 to 5 would be necessary, and decided to report the outcome at the GOM scheduled on Monday, February 26.

In addition, in parallel with these developments, the Central R&D Laboratory and the Food Department considered the possibility that some kind of toxic substance was being generated or mixed in. Specifically, the Food Department analyzed known mycotoxins (other than fungal toxin citrinin) and heavy metals, and the Central R&D Laboratory examined an exhaustive comparative composition analysis, including for unknown components, respectively. The known mycotoxin analysis (other than fungal toxin citrinin) had started being examined before the Feb. 22 Medical Doctor Interview, but after the Feb. 22 Medical Doctor Interview the possibility that some kind of toxic substance was being generated or mixed in began to attract greater suspicion, and preparations for conducting the necessary testing therefor and other preparations began to proceed.

3.7.2 Status of Discussions at the Feb. 26 GOM

On Monday, February 26, a regular GOM was held (the "**Feb. 26 GOM**"). At the Feb. 26 GOM, the outcome of the Feb. 22 Medical Doctor Interview for Cases 3 to 5 was reported. Namely, it was reported to the effect that (i) the cause of Cases 3 to 5 was thought to be tubulointerstitial nephritis caused by an allergic reaction and not rhabdomyolysis, (ii) for Case 5, the causal relationship was marked as "Definite,"[38] and (iii) for Cases 3 and 4, the causal relationship was marked as "Probable" and the possibility of toxicity was also mentioned. A report was also made on the proposal from Medical Doctor B for adding a note to the precautions for ingestion.

Based on this report, at the Feb. 26 GOM the attendees considered whether or not conducting reporting to governmental authorities would be necessary. It was at the Feb. 26 GOM that the Senior General Manager of the Pharmacovigilance & Consumer Relations Division explained for the first time that, although the standards for conducting reporting to governmental authorities for Foods with Function Claims were "if there is a risk of occurrence and spread of health damage," because there were no clear standards

[38] As stated in footnote 36.

for determining an "occurrence of health damage," Kobayashi Pharmaceutical had set its own interpretation to conduct reporting to governmental authorities "only when a causal relationship was clear," which was in accordance with the standards used for the foods for specified health uses (*tokutei hoken-yo shokuhin*). Because there had not been progress in the analysis of the cause as of the time of the Feb. 26 GOM, the causal relationship was not clear, and the GOM attendees did not determine that there was a "risk of spread," so the attendees at the Feb. 26 GOM did not come to the conclusion that reporting to governmental authorities would be necessary.

Furthermore, regarding the necessity of reporting to governmental authorities, there was a statement in the Feb. 26 GOM materials to the effect that "determine whether or not to conduct reporting to governmental authorities after discussing with attorneys and experts and carefully examining the causal relationship and seriousness from both medical and pharmacological perspectives, and taking into account the reputational risk and impact on the business."

3.7.3 Discovery of Case 10 and Subsequent Communication with the Doctor in Charge

On Tuesday, February 27, the Customer Relations Office of Kobayashi Pharmaceutical was contacted by C, a medical doctor who worked at Hospital γ, located in the Kinki Region ("**Medical Doctor C**"). Medical Doctor C stated that Medical Doctor C had a patient who had ingested the Product who had a serious case of kidney problems and would be undergoing a biopsy; this patient had developed the symptoms about one to two months after beginning to ingest the Product (Case 10). For this, because Medical Doctor C suspected drug-induced kidney problems in the patient in Case 10, Medical Doctor C inquired with the Customer Relations Office as to whether it was possible to measure the level of citrinin in the remaining Product which the patient possessed.

Within Kobayashi Pharmaceutical, at around 5:30 p.m. on Tuesday, February 27, the person in charge in the Pharmacovigilance Group shared the content of the communication from Medical Doctor C by email with the Senior General Manager of the Pharmacovigilance & Consumer Relations Division, the Food Department Head, the Pharmacovigilance Department Manager, and other members concerned. Around the same time, the Pharmacovigilance Department Manager informed the Senior General Manager of the Pharmacovigilance & Consumer Relations Division of the situation by sending a separate email thereto. In addition, at around 6:00 p.m. that day, the Food Department Head informed the Senior General Manager of the Healthcare Products

Headquarters of the situation by email.

On Thursday, March 7, the person in charge in the Pharmacovigilance Group telephoned Medical Doctor C, heard that the names of the diagnoses for the patient in Case 10 were tubulointerstitial nephritis,[39] and requested Medical Doctor C a detailed investigation. Medical Doctor C agreed to confirm with the patient in Case 10 whether or not the patient would consent to be subject to such detailed investigation, and also to confirm whether it would be possible for Kobayashi Pharmaceutical to come to the hospital and conduct the detailed investigation. Further, regarding the inquiry from Medical Doctor C concerning the level of citrinin, the person in charge in the Pharmacovigilance Group responded (in that same phone call) that no citrinin had been detected in any of the ingredient lots.

3.7.4 Detailed Investigation on Medical Doctor A of Hospital α

On Thursday, February 8, the person in charge in the Pharmacovigilance Group sent an email to Medical Doctor A of Hospital α, who was the doctor in charge in Case 1, and requested Medical Doctor A to have an interview with Kobayashi Pharmaceutical, by proposing the period from Tuesday, February 20 to Thursday, February 29 as potential interview dates. After exchanging several telephone calls, the interview between Medical Doctor A and Kobayashi Pharmaceutical was set for Thursday, February 29 (the "**Feb. 29 Medical Doctor Interview**"; collectively with the Feb. 22 Medical Doctor Interview, the "**Medical Doctor Interviews**").

The Food R&D Group Manager, the Pharmacovigilance Group Manager, and other persons concerned interviewed Medical Doctor A from 4:00 p.m. to 4:30 p.m. on Thursday, February 29 at Hospital α.

According to Medical Doctor A, Case 1 was (i) not rhabdomyolysis, but tubulointerstitial nephritis, the seriousness of which was "life threatening," and, (ii) although a toxic or allergic nature was suspected as a cause, the details were unknown because Medical Doctor A had not received the results of the DLST, and (iii) although Medical Doctor A could not say there was a clear causal relationship between the Product and the kidney problems, Medical Doctor A had observed that the kidney problems had occurred about two weeks[40] after the patient began ingesting the Product, and therefore a correlation in terms of time between the ingestion of the Product and the kidney problems

[39] The exact record showed the names "acute tubular disorder and interstitial nephritis."
[40] As stated in 3.2.1 above, the duration of ingestion of the Product prior to the onset of the symptoms had already been told to Kobayashi Pharmaceutical as of January 31.

could not be denied. Medical Doctor A also stated Medical Doctor A's own opinion that there were no other factors[41] that Medical Doctor A could think of other than the Product.

Then, based on the contents of the Feb. 29 Medical Doctor Interview, the attendees of said Interview thought of another possibility: that a separate factor that had triggered the kidney problems might be present in the product lot (H3017)[42] that had been ingested by the patient in Case 1. Accordingly, in order to test the Products with the same lot number, immediately following the ending of the Feb. 29 Medical Doctor Interview, the attendees at said Interview visited drugstores in the city in which Hospital α is located and purchased Products with the same lot number.

At around 8:00 p.m. on Thursday, February 29, the Pharmacovigilance Group Manager shared the information on the gist of the Feb. 29 Medical Doctor Interview by email as a quick update with the members in the Quality Assurance Department, Pharmacovigilance Department, the Food Department, and the Direct Marketing Division. Then, from 11:00 a.m. on Friday, March 1, an online meeting was held with persons concerned, including the Senior General Manager of the Healthcare Products Headquarters and the Senior General Manager of the Pharmacovigilance & Consumer Relations Division, at which the information of the details of the Feb. 29 Medical Doctor Interview was shared again and a discussion was held on the contents to be reported at the next GOM to be held on Tuesday, March 5. In addition, after the online meeting, it was agreed to purchase and collect more of the Products of that particular lot number (i.e., H3017), as well as Products with the product lot number produced before and after that product lot (H3017). In response to the aforesaid, on the same day, each department and division related to a product that contained red yeast rice (such as the Food Department, the Quality Management Department of the Healthcare Products Headquarters, the Healthcare Technology Development Department of the Development and Procurement Division of the Manufacturing Headquarters, and the R&D Department) and other staff members of the Pharmacovigilance & Consumer Relations Division was requested to search for and purchase those products in the Osaka area.

[41] On the detailed interview sheets for Case 1, the checkbox in the "causal relationship" column was marked as "Possible."

[42] As stated in 3.2.1 above, this exact lot number had already been told to Kobayashi Pharmaceutical as of February 8.

3.7.5 Status of Discussions at the Mar. 4 TEAM-F Meeting

On Monday, March 4, a regular TEAM-F meeting[43] was held (the "**Mar. 4 TEAM-F Meeting**"). At the Mar. 4 TEAM-F Meeting, the state of the information sharing with the Outside Directors became a topic of discussion. Full-time Audit and Supervisory Board Member Kawanishi raised the issue of that a certain level of important management matters and information that could lead to serious risks from among the agenda items discussed at the GOMs should be shared with the Outside Directors, and he mentioned the Issue and other matters as examples of information that could lead to a serious risk. Further, Full-time Audit and Supervisory Board Member Kawanishi pointed out that, as a general matter, there were no internal rules regarding the sharing of risk information with Outside Directors at Kobayashi Pharmaceutical, and that matters concerning such decision-making were unclear. Full-time Audit and Supervisory Board Member Kawanishi recommended that the procedures for sharing risk information with Outside Directors should be clarified, for example, by establishing certain standards. In response to this proposal, as a result of the discussion, Senior Executive Director Yamane instructed the General Manager of the Management Planning Department of the Sustainability Management Headquarters, to compile a risk management report from the GOMs and report thereon to the Outside Directors as an information sharing measure for the Outside Directors going forward. However, as a result of the deliberations at the general manager meeting at which the General Manager of the Management Planning Department of the Sustainability Management Headquarters and others participated, although a policy for the Monthly Risk Committee[44] to select certain important management matters to share with the Outside Directors was agreed upon, there were no specific deliberations held regarding information sharing pertaining to the Issue.

As stated in 3.9.4 below, the Issue was not shared with the Outside Directors until March 20.

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[43] TEAM-F is a meeting held monthly at which the Representative Director and President, the Senior Executive Director and full-time Audit and Supervisory Board members attend, and the Management Planning Department serves as its secretariat. The TEAM-F is held according to Article 16 (Regular Meetings with Representative Directors) of the Code of Audit and Supervisory Board Member Auditing Standards. During TEAM-F, either of the two full-time Audit and Supervisory Board in turn, or both of them together, give a report to the Representative Director and President on any concerns regarding the execution of business in the process of daily auditing and exchange their opinions.

[44] The Monthly Risk Committee is a meeting body for examining monthly reports and extracting risk information that should be reported in the GOM. The Risk Management Department of the Sustainability Management Headquarters served as the Monthly Risk Committee's secretariat and all general managers in the corporate departments were to attend the meetings.

3.7.6 Status of Discussions in the Mar. 5 GOM

On Tuesday, March 5, a regular GOM was held (the "**Mar. 5 GOM**"). At the Mar. 5 GOM, the cases that had come to light after the Feb. 26 GOM were reported (those being Cases 6 and 9 as outpatient cases and Case 10 as a hospitalization case), and the outcome of the Feb. 29 Medical Doctor Interview was also reported. Namely, it was reported that Case 1 was a case of tubulointerstitial nephritis, not rhabdomyolysis, and the cause, though unclear, was suspected as potentially being either an allergic reaction or toxic substance, and the causal relationship had been marked as "Possible." However, it was also reported that the DLST results had not yet been obtained and that the seriousness of the illness of the patient in Case 1 was "life threatening."

Then, at the Mar. 5 GOM, it was decided that a second opinion from experts regarding the causal relationship, seriousness, and cause would be obtained and carefully examined, and thereon, determine the necessity of conducting reporting to governmental authorities and other matters. It was also reported that consultations were planned with attorney and medical doctor P for Wednesday, March 6 and with attorney Q for Wednesday, March 13.

In addition, due to the fact that, as with Medical Doctor B, Medical Doctor A had also denied rhabdomyolysis attributable to monacolin K as the possible cause, the attendees at the Mar. 5 GOM discussed having the Central R&D Laboratory and the Food Department conduct an exhaustive presumptive cause-by-cause examination, not limited to only monacolin K.[45] Depending on the presumptive cause, it was estimated that the examination process would take until the end of August, at the latest. Senior Executive Director Yamane and other attendees of the GOM asked the Head of the Central R&D Laboratory whether the examination schedule could be accelerated forward, but the Head of the Central R&D Laboratory responded to the effect that it would be impossible to further expedite the process because certain tests would need to go through animal testing using rats.

3.8 Consultation with External Experts and Responses Thereafter

3.8.1 Background of External Expert Consultations

The background up to Kobayashi Pharmaceutical consulting with external experts such

[45] However, even putting aside the question of what the exact cause of the Cases was, given that the excessive ingestion of monacolin K could be harmful to the human body, measures such as setting an upper limit of content for the monacolin K in the Product and adding a statement to Product inserts to the effect of precautions when ingesting, continued to be considered.

as medical doctors and attorneys concerning the Issue is as previously stated in 3.7.6 above.

The external expert consultations were led by the Domestic Quality Assurance Group and the Pharmacovigilance Group, and both were responsible for selecting the external experts, making appointments and scheduling, preparing materials, and other similar preparations. The Pharmacovigilance Department selected attorney and medical doctor P as an external expert to consult with, with the primary purposes being to obtain a second opinion on the existence of a causal relationship from the perspective of a medical doctor, to receive advice on whether or not to conduct reporting to governmental authorities from the perspective of an attorney, as well as to have attorney and medical doctor P refer a nephrologist to Kobayashi Pharmaceutical. In addition, the Domestic Quality Assurance Group selected attorney Q as an external expert to consult with on the necessity of and criteria for conducting reporting to governmental authorities. Attorney Q had the experience of having been seconded to the Consumer Affairs Agency, and attorney Q was the attorney with whom the Domestic Quality Assurance Group had regularly and previously consulted with regarding the Premiums Representations Act[46] and other laws and regulations related to food products.

Specific scheduling with each of these external experts were handled by a person in charge in the Domestic Quality Assurance Group, and the dates on which to schedule the attorney consultations were picked from early March,[47] on the assumption that the Medical Doctor Interviews would be finished by the time that Kobayashi Pharmaceutical would have the actual consultations with these external experts.[48]

3.8.2 Consultation with Attorney and Medical Doctor P

On Tuesday, February 27, the day immediately after the Feb. 26 GOM, a person in charge at Kobayashi Pharmaceutical requested attorney and medical doctor P to have a consultation session primarily on how to approach the causal relationship and whether or

[46] Act against Unjustifiable Premiums and Misleading Representations (Act No. 134 of May 15, 1962).
[47] However, the consultation with attorney Q as stated in 3.8.5 below was scheduled for March 13 due to circumstances such as attorney Q being overseas on business.
[48] The person in charge in the Domestic Quality Assurance Group, who was in charge of arranging the dates for the external expert consultations, explained that the reason for conducting the external expert consultations after the Medical Doctor Interviews were finished was because having results from only one detailed investigation on a medical doctor might not have produced enough facts on which to base the attorney consultations and, if so, the attorney consultations might have ended with only abstract advice being given. However, there were also individuals who stated that they had not thought that they could not conduct the outside expert consultations until the interviews with both medical doctors were complete.

not to conduct reporting to governmental authorities, both based on specific cases. The consultation with attorney and medical doctor P was held from 11:30 a.m. to 1:00 p.m. on Wednesday, March 6 (the "**Mar. 6 External Expert Consultation**"). The Senior General Manager of the Pharmacovigilance & Consumer Relations Division, the Pharmacovigilance Department Manager and the subordinate staff members thereof in the Pharmacovigilance Department, the Quality Assurance Department Manager, the Food Department Head, and other persons concerned attended the Mar. 6 External Expert Consultation, which was held at Kobayashi Pharmaceutical.

During the Mar. 6 External Expert Consultation, the attendees mainly discussed matters [49] such as the appropriateness of Kobayashi Pharmaceutical's criteria for conducting reporting to governmental authorities, the necessity of conducting reporting to governmental authorities at this point in time or in the future, and whether or not Kobayashi Pharmaceutical could continue selling the Products. Attorney and medical doctor P also expressed attorney and medical doctor P's own view on possible causes of the Cases.

Attorney and medical doctor P also pointed out that, regarding the cause of the Cases, Kobayashi Pharmaceutical should consider a cause other than Monascus fungus and the possibility of the red yeast rice generating some other substance(s) because the number of communications regarding kidney malfunction related to the Product had increased rapidly in a short period of time, and, in attorney and medical doctor P's opinion, monacolin K or allergies attributable to red yeast rice were unlikely to be considered as the cause because if they had been, attorney and medical doctor P would expect similar cases to have been reported from before, but on the other hand, it is too high a probability to be coincidence, given that five cases (from three medical institutions) had been reported by the medical doctors. Attorney and medical doctor P further stated that it was possible to conclude that product lot(s) manufactured in a certain period of time may be the cause, because the timing of occurrence of the Cases was concentrated within a short timeframe, and attorney and medical doctor P advised that that if the production periods, product lots, and the like of the Product that had been ingested by the patient in each Case

[49] The consultation materials prepared for the Mar. 6 External Expert Consultation included a list of Cases 1 to 10, which had been discovered as of that time on Monday, March 4 (the date on which the materials were prepared), with the cases being separated by instances of hospitalizations and the instances of outpatient consultations (and also included the dates on which Kobayashi Pharmaceutical received the information, manner of sale, information sources, and symptoms/name of diagnosis/ingestion periods). These case details were written for Case 1 and for Cases 3 to 5, the cases for which Kobayashi Pharmaceutical had commenced the detailed investigation on medical doctors as of that point in time. Further, the name of the diagnosis of the patient in Case 10, namely tubulointerstitial nephritis, was not known as of the time of this consultation with attorney and medical doctor P.

could be identified, then given the symptoms that had occurred it might be advisable to investigate the product lots that had been ingested immediately (two to three weeks) prior to the manifestation of those symptoms.

Regarding whether or not reporting to governmental authorities would be necessary, attorney and medical doctor P stated attorney and medical doctor P's own view to the effect that, in general, it is desirable to submit a report to the relevant authorities even if there is no legal obligation to do so, although attorney and medical doctor P did not believe that Kobayashi Pharmaceutical was at that time in a situation where immediate and mandatory reporting would be required. In addition, attorney and medical doctor P responded that there was no problem with the interpretation and grounds for conducting reporting to governmental authorities established by Kobayashi Pharmaceutical stated in 4.2.3 below, which stated that reporting to governmental authorities is required "only when the causal relationship is clear," in the sense that attorney and medical doctor P did not believe such interpretation deviated from the "Guidelines on Notification of Foods with Function Claims (Revised on September 29, 2023) (CFL Notification No. 543)" of the Consumer Affairs Agency (the "**Notification Guidelines**").[50] Furthermore, attorney and medical doctor P continued by stating an opinion to the effect that, as of this time at the Mar. 6 External Expert Consultation, based on the components of the Product, it had to be said that the possibility of any causal relationship between the Product and Case 1 and the Product and Cases 3 to 5, respectively, was low, and that conditions for conducting reporting to governmental authorities at that point in time had not yet been fully met. That said, however, attorney and medical doctor P also stated an opinion to the effect that attorney and medical doctor P had doubts based on experience on the fact that multiple case reports were received within a short period of time that focused on tubulointerstitial nephritis, and as such, if Kobayashi Pharmaceutical received one to two more reports of other serious symptoms of nephritis, including tubulointerstitial nephritis, then, because this would mean that Kobayashi Pharmaceutical had received reports from four to five medical institutions in total, Kobayashi Pharmaceutical should, as a corporate decision, start corresponding with administrative authorities, including by conducting reporting to governmental authorities, without waiting for the cause to be identified.

Regarding whether or not it was possible for Kobayashi Pharmaceutical to continue selling the Products, attorney and medical doctor P stated an opinion to the effect that, at this point in time, the appropriate action would be to suspend advertising of the Products

[50] However, in an interview with the Committee, as a summary, attorney and medical doctor P stated that attorney and medical doctor P had understood the wording "causal relationship is clear" to have a meaning which extended to "a substance that could develop kidney problems."

because the cause was still unclear, but if Kobayashi Pharmaceutical received one to two more case reports of serious symptoms of nephritis, including tubulointerstitial nephritis, from that point on, then Kobayashi Pharmaceutical should, as a corporate decision, consider conducting a product collection and discontinuing sales of the Products without waiting to identify the cause.

3.8.3 Investigation into the Product Lots Ingested by the Patients in Each Case

In response to the advice it received at the Mar. 6 External Expert Consultation stated above in 3.8.2 to the effect that it would be advisable to investigate the product lots that had been ingested immediately (two to three weeks) prior to the manifestation of the symptoms of the patients in each case, Kobayashi Pharmaceutical once again attempted to identify the product lots of the Product that the patients in each Case had ingested.

Namely, the Food R&D Group Manager, who had attended the Mar. 6 External Expert Consultation, believed that for the investigations into the product lots in each case, of which Kobayashi Pharmaceutical had only been partially aware, it might be possible to infer or identify those product lots by comparing them with the direct marketing records, and the Food R&D Group Manager confirmed this with the Direct Marketing Department.

Specifically, the Food R&D Group Manager noticed the following three points: (i) that product lot H306 was common between and had been included in the Product that had been ingested by each of the patients in Cases 2, 6, and 8, all of whom were direct marketing customers, (ii) that the H306 product lot had been manufactured using ingredient lot 320-23726R, and (iii) that lot H3017, which was the product lot of the Product that had been ingested by the patient in Case 1, who had purchased the Product over the counter, was also manufactured using a portion of ingredient lot 320-23726R,[51] which was shared with product lot H306. The Food R&D Group Manager then believed there was a possibility that, for the direct marketing Product, the cause of the Cases might be found in the H306 product lot. The Food R&D Group Manager then requested the Direct Marketing Department Head and the Operations Management Group Manager of the Direct Marketing Department to confirm the delivery date of the Product related to each lot shipped to each patient in Cases 2, 6, and 8, all of whom had been direct marketing customers, and to confirm whether a Product related to the H306 product lot had been shipped to the patient in Case 4, who was known to have ingested a Product pertaining to the X304 product lot. The Food R&D Group Manager also requested the

[51] The H3017 product lot was manufactured by blending ingredients from lots 320-23726R and 320-23627R at a 6-1 ratio.

Direct Marketing Department Head and the Operations Management Group Manager of the Direct Marketing Department to confirm whether it was possible that the other patients had been direct marketing customers, and if so, whether there were any facts that any Product related to the H306 product lot had been shipped to such patients. In response to this, the Direct Marketing Department proceeded with said confirmations, and as a result, during the day on Thursday, March 7, it became clear that there was a possibility that the patients in Cases 2 to 6 and Case 8 had received shipments of and ingested Products which pertained to the H306 product lot immediately prior to the onset of their symptoms. On the evening of Thursday, March 7, the Food R&D Group Manager shared these results with relevant individuals in, among others, the Food Department, including the Food R&D Group Manager's superior the Food Department Head, the Pharmacovigilance Department, the Direct Marketing Department, and the Central R&D Laboratory.

Furthermore, in parallel with the developments in these lot investigations, in response to the advice from attorney and medical doctor P to the effect that it would be advisable to investigate the product lots that had been ingested immediately (two to three weeks) prior to the manifestation of the symptoms of the patients in each case, on Thursday, March 7, the Quality Assurance Department decided on an investigation plan to also verify the possibility of any kind of unknown substance being mixed into the Product (any contamination) during the manufacturing process at the Osaka Plant, which had been manufacturing the red yeast rice ingredients as of 2023, or during the manufacturing process at the outsourcing company, which had been subcontracted to perform a portion of the manufacturing process for the Product as of 2023. This investigation was conducted by members including the Quality Assurance Department Manager, the Domestic Quality Assurance Group Manager, and the staff members of the Quality Assurance Department, and on Friday, March 8, after coordinating with the persons in charge on the Manufacturing Headquarters side, a kick-off meeting was set for Tuesday, March 12. In the meantime, the Domestic Quality Assurance Group conducted examinations of the lots subject to the investigation, prepared materials for the kick-off meeting, and carried out other duties with the persons in charge in the Food R&D Group.

As a result of the kick-off meeting held on Tuesday, March 12, the participants decided to not conduct the investigation of the manufacturing process at the outsourcing company on the grounds that, at that time, it was a relatively low priority. For the investigation of the Osaka Plant, the relevant persons at Meitanhompo was required to carefully examine again the manufacturing record documents that were being kept at that time, giving

priority to ingredient lot 320-23726R and the corresponding culture lots.[52] In doing so, the manufacturing record documents were checked to find whether there were any kind of deviations, in greater detail compared to the investigation into deviations in the manufacturing process conducted in early February as described above in 3.4.3, such as, for example, making any past accidents also subject to the investigation. However, as far as the careful examination of the documents was concerned, this investigation did not reveal any particular deviations or the like.

3.8.4 Status of Discussions, Etc. in the Mar. 12 GOM

On Tuesday, March 12, a regular GOM was held (the "**Mar. 12 GOM**"). At the Mar. 12 GOM, regarding the outcome of the Mar. 6 External Expert Consultation, it was reported that (i) it was the view of attorney and medical doctor P that some sort of hazardous components being mixed into the Products was a possible cause, (ii) an allergy as a possible cause was unlikely because if that were true, then the allergies should have occurred from around the time when the Product was first launched, (iii) although attorney and medical doctor P supported the criteria of Kobayashi Pharmaceutical for reporting to governmental authorities, which stated that reporting to governmental authorities would need to be conducted only when a causal relationship was clear, attorney and medical doctor P expressed the view that attorney and medical doctor P recommended conducting reporting to governmental authorities or asking for administrative counseling and to discontinue advertising for the Products if two new hospitalization cases were added in the future, and (iv) attorney and medical doctor P furthermore recommended proceeding with the analysis of certain product lots.

In addition, it was reported at the Mar. 12 GOM that a second opinion regarding the determination of a causal relationship was scheduled to be obtained from S, a medical doctor at a hospital affiliated with a national university in Japan ("**Medical Doctor S**") on Monday, March 18, with attorney and medical doctor P in attendance. Moreover, it was reported that three new instances of outpatient cases (Cases 11 to 13) had been added and that the names of the diagnoses for the patient in Case 10 were found to be acute tubular disorder and interstitial nephritis.

3.8.5 Consultation with Attorney Q and Attorney and Medical Doctor R

[52] As previously stated in 2.5.2, ingredient lots are manufactured by blending multiple culture lots. "The corresponding culture lots" means the multiple culture lots that were mixed into ingredient lot 320-23726R.

On Monday, February 26, after the Feb. 26 GOM, a person in charge at Kobayashi Pharmaceutical's Pharmacovigilance & Consumer Relations Division requested a consultation with attorney Q, primarily to consult on matters such as the causal relationship between the Products and each of the Cases, the appropriateness of the response measures taken with respect to the Issue, including reporting to governmental authorities, and the responsibilities required as a business-to-business ingredients manufacturer. This consultation was held through an online meeting from 5:30 p.m. to 8:00 p.m. on Wednesday, March 13 (the "**Mar. 13 External Expert Consultation**"). Further, as per attorney Q's judgment, R, an attorney with also a medical license, was also present at the Mar. 13 External Expert Consultation (together with attorney Q, hereinafter collectively, "**Attorneys Q and R**"). The attendees at the Mar. 13 External Expert Consultation were the Quality Assurance Department Manager and the subordinate staff members thereof in the Quality Assurance Department, the Senior General Manager of the Pharmacovigilance & Consumer Relations Division, the Food Department Head, the Pharmacovigilance Department Manager, and other persons concerned.

At the Mar. 13 External Expert Consultation, Attorneys Q and R expressed their opinion that, with regard to the causal relationship between the Product and Case 1 and the Product and Cases 3 to 5, respectively, for starters, a causal relationship was strongly suspected in Case 5, due to facts such as that the medical doctor suspected, as the medical doctor's diagnosis, that the cause was symptoms resulting from allergies and that the DLST results were positive but there were no other suspect drugs. On the other hand, when viewed individually, Cases 1, 3 and 4 were highly likely not be deemed to have any causal relationship. In particular, Cases 3 and 4 were cases observed at the same medical institution as Case 5, which suggested that the diagnostic judgment in Case 5 may have influenced the judgment in Cases 3 and 4.

In addition, for reporting to governmental authorities, by referring to the causal relationship screening sheet that had been used as the reference materials for the report from the Consumer Affairs Agency titled "Survey and Inspection Program Concerning Implementation Status for Analysis after Submitting Notification of Foods with Function Claims and Information Collection on Heath Issues, Etc.," Attorneys Q and R expressed their opinion that Cases 1, 3 and 4 were not subject to reporting to governmental authorities, and that Case 5 could be assessed as falling under the category in which a causal relationship was "highly possible," but as such, Case 5 was the only case that could be so assessed as of the time, and it could be considered to be an instance of idiosyncratic allergic symptoms. Therefore, Attorneys Q and R believed that Case 5 could not be said

to meet the criterion of a "risk of spread" from among the reporting criteria stated in 4.2.3 below and that the Cases were not subject to reporting. However, Attorneys Q and R further expressed their opinion that Kobayashi Pharmaceutical should continue investigating and collecting information on any event that raised concerns about the "risk of spread," including any occurrences of cases of suspected similar allergic reactions and checking for any unanticipated substances that may have been mixed, the checks of which were then currently underway.

Furthermore, Attorneys Q and R pointed out that if Kobayashi Pharmaceutical had only suspended the advertisements for the Products, that act could be construed as if Kobayashi Pharmaceutical would continue to sell the Products while knowing that the Products themselves posed a risk at that point in time. In addition, Attorneys Q and R expressed their views that it would be natural to suspend advertising in conjunction with the discontinuation of sale, thus, so long as Kobayashi Pharmaceutical was working under the hypothesis by the medical doctors of instances of allergic symptoms, Kobayashi Pharmaceutical had as of now not yet reached that phase of suspending the advertisements.

3.8.6 Approach of Kobayashi Pharmaceutical Following the Mar. 13 External Expert Consultation

Based on the views of Attorneys Q and R that Kobayashi Pharmaceutical received at the Mar. 13 External Expert Consultation, Kobayashi Pharmaceutical did not engage in deliberations to immediately conduct reporting to governmental authorities or conduct a product collection. As of Wednesday, March 13, there were two scenarios being considered within Kobayashi Pharmaceutical as leading hypotheses: (i) "the possibility that some toxic substances had been mixed into a certain product lot," which was based on the view expressed by attorney and medical doctor P, and (ii) "the possibility of an allergic reaction resulting from a peculiarity of each individual patient," which was based on the view indicated by Attorneys Q and R. The Senior General Manager of the Pharmacovigilance & Consumer Relations Division was inclined to consider the latter scenario first while maintaining the investigation into the former scenario because in the former scenario, forecasts were indicating that it would take more time to determine the cause; for example, the Mar. 12 GOM materials indicated that receiving results would take until at least the first week of April.

In addition, on Thursday, March 14, Chairman & CEO Kobayashi sent an email to President & COO Kobayashi once again proposing that Kobayashi Pharmaceutical should refrain from advertising the Products for the time being if there was a possibility of

conducting a product collection for the Products. To this, the Senior General Manager of the Pharmacovigilance & Consumer Relations Division, who had received the same email because the email address thereof was carbon copied thereto, and the Food Department Head, who had an appointment with Chairman & CEO Kobayashi for a meeting on that same day, respectively explained to the effect that, based on the outcome of the Mar. 13 External Expert Consultation, a report would be made at the next GOM stating that (i) not conducting reporting to governmental authorities at this point would be appropriate, (ii) the policy of the Healthcare Products Headquarters was to continue maintaining the current advertising, and (iii) the current advertising was untouched at that point. On the same day, President & COO Kobayashi was overseas on business and thus read the email from Chairman & CEO Kobayashi after these exchanges, so he did not reply to the email.

3.9 Discovery of Peak X

3.9.1 Detection of Peak X

Based on the results of the lot investigation as previously stated in 3.8.3, the Central R&D Laboratory conducted an HPLC analysis[53] using a multi-wavelength detector on 84 lots of the Product sold from July 2022 onward and confirmed the analysis chart from a detection wavelength of 254nm. On Friday, March 15, the results of this HPLC analysis detected an unknown peak[54] ("**Peak X**"), which indicated that there was a possibility that a component which Kobayashi Pharmaceutical did not intentionally include was contained in a portion of the lots, including in the production lots previously mentioned in 3.8.3 (H306 and H3017), which were the product lots that the patients in each of the Cases had either consumed or possibly consumed.

Following this, in addition to continuing the analysis of Peak X, on Friday, March 15,

[53] An HPLC analysis is an analytical method in which components in a liquid are separated and detected by passing them through a stationary phase called a column. By using the fact that the time for each component to pass through a column varies depending on the properties of the component, an HPLC analysis attempts to identify each component based on the time it takes for the components to be detected. Further, a muti-wavelength detector is an instrument capable of measuring a certain wavelength range and can obtain three-dimensional data on a retention time axis, peak intensity axis, and wavelength axis. It can also produce analysis data for each wavelength after an analysis has been conducted as long as those wavelengths are within the measured wavelength range. At Kobayashi Pharmaceutical, as a multi-wavelength detector (with a detection wavelength of 200nm to 500nm) is used for the pre-shipment inspections of ingredients and cultures, it is possible to retrospectively produce and confirm an analysis chart used for the ingredients and cultures for each wavelength within a range of 200 to 500nm.

[54] A "peak" means the part on the analysis chart generated from the result data of an HPLC analysis where the waveform is high, which indicates that a component was detected.

in order to confirm the existence of Peak X in the red yeast rice ingredients at the time of shipment, the Central R&D Laboratory confirmed the analysis chart from a detection wavelength of 237nm generated from the HPLC analysis data from the pre-shipment inspections of 33 ingredient lots from its factory.[55] As a result, Peak X was found in a portion of these ingredient lots. Until this time, the HPLC analysis data at the time of production of the Product, nor for its ingredients or cultures, had not been sent for.

Furthermore, between Friday, March 15 and Saturday, March 16, in order to verify the reproducibility of the abovementioned analysis confirmation data, the Central R&D Laboratory conducted an HPLC analysis using a multi-wavelength detector on the stored samples of the ingredients (the 33 ingredient lots used in the Product sold since July 2022). As a result of the analysis chart from a detection wavelength of 237nm, Peak X was detected in some of the ingredients. In response to this, testing was continued from the start of the following week on Monday, March 18[56] using the analysis chart of from a 270nm detection wavelength, which was the detection wavelength at which Peak X was the most visible.

Despite the fact that a peak had also existed on the analysis chart of some of the lots from a detection wavelength of 237nm, as stated above, which had been how Kobayashi Pharmaceutical had been conducting confirmations in the HPLC analysis as one of the pre-shipment inspections, Kobayashi Pharmaceutical had been unable to notice this. The reasons for this included the following: (i) the HPLC analysis itself for the Product was conducted for the purpose of confirming the amount of monacolin K content, the valuable ingredient of the Product as a Food with Function Claims, (ii) it was normal for multiple peaks to appear in the HPLC analysis for the red rice yeast ingredients, which are natural fermented products, because such products contain a large amount of trace elements other than monacolin K, and (iii) although Peak X was most visible at a detection wavelength of 270nm, when confirming the HPLC analysis results, Kobayashi Pharmaceutical had only been checking the analysis chart from a detection wavelength of 237nm, which is the most appropriate for confirming the amount of monacolin K content.

3.9.2 Response following the Detection of Peak X

On the morning of Sunday, March 17, the Food R&D Group Manager reported to the Food Department Head by email on the fact that Peak X had been discovered, as

[55] Confirmation of the analysis chart from a detection wavelength of 237nm was also conducted at the time of the pre-shipment inspection.
[56] No confirmations or verification were conducted on Sunday, March 17 as it was a non-working day.

previously stated in 3.9.1. That afternoon, the Food Department Head then reported to the Senior General Manager of the Healthcare Products Headquarters and the Senior General Manager of the Pharmacovigilance & Consumer Relations Division by email on the discovery of Peak X as a quick update.

In response to the abovementioned report, in the evening of Sunday, March 17, the Senior General Manager of the Pharmacovigilance & Consumer Relations Division sent an email[57] to Chairman & CEO Kobayashi and the GOM members which stated that: (i) it had been discovered as a result of the detection of Peak X that an unintended substance had been mixed into the product lots from batch H306 of the Product; (ii) the name of the substance had not been identified; (iii) the details and reason why this mixing had occurred was unclear; (iv) the Senior General Manager of the Pharmacovigilance & Consumer Relations Division believed that it was now at the stage where decisions on when to suspend consumer use of the Product and introduce a product collection is required, and that these points need to be discussed and decided at the GOM meeting to be held on Tuesday, March 19, and; (v) there should be an emergency meeting held with the relevant departments on Monday, March 18 to discuss the actions going forward and the timing of issuing a press release. In addition, following this, the Senior General Manager of the Pharmacovigilance & Consumer Relations Division sent an email to the primary senior general managers and general managers in the Healthcare Products Headquarters, Manufacturing Headquarters, Sustainability Management Headquarters, and Pharmacovigilance & Consumer Relations Division, requesting their participation in the emergency meeting to be held from 2:00 p.m. on Monday, March 18. With regards to this, in response to the email sent by the Senior General Manager of the Pharmacovigilance & Consumer Relations Division, Senior Executive Director Yamane requested the Senior General Manager of the Pharmacovigilance & Consumer Relations Division to give an explanation of the situation at the BRM[58] scheduled to be held on Monday, March 18, given the fact that the content of the report was highly urgent.

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[57] This email was sent to the GOM group email address, which included some GOM members including President & COO Kobayashi and Senior Executive Director Yamane (Chairman & CEO Kobayashi, the Senior General Manager of the Pharmacovigilance & Consumer Relations Division, and the Food Department Head were carbon copied in the email). However, the Committee obtained several statements to the effect that due to a sending error, some members with this group email address did not receive this email. It is highly likely that some of the members who did not receive this email were only informed of the content in the email through the report given at the BRM (see footnote 58) and the requests for their attendance at the emergency meeting.

[58] "BRM" is an abbreviation for the "Bridge Meeting," which is an unofficial meeting body convened twice a month at which various business reports and other reports are given to Chairman & CEO Kobayashi, President & COO Kobayashi, and Senior Executive Director Yamane according to agendas compiled by the Management Planning Department.

At the BRM held between 9:30 a.m. and 10:00 a.m. on Monday, March 18 (the "**Mar. 18 BRM**"), the Senior General Manager of the Pharmacovigilance & Consumer Relations Division and the Food Department Head gave an explanation to Chairman & CEO Kobayashi, President & COO Kobayashi, and Senior Executive Director Yamane using some of the materials for the GOM to be held on Tuesday, March 19 on the product lots from batch H306 of the Product, the fact that Peak X was detected in the red yeast rice ingredient lots thereof, and other matters. As a result, although the relationship between Peak X and the Cases was still unclear, because the possibility of Peak X and the Cases being related could not be denied and because there was also a risk of similar cases occurring going forward, a plan was adopted to promptly halt shipments of the Product and conduct a product collection, as well as to issue a press release and product warning. A plan was decided to issue around Friday, March 22 a press release stating to the effect that the Product was being collected, considering the fact that several days would be required for the analysis to clarify the specific causative agents.

After this, an emergency meeting concerning the Product was held at 2:00 p.m. on Monday, March 18. At this emergency meeting, in order to avoid spreading more information than was necessary given the fact that the cause of the substance responsible for Peak X being mixed was still unclear, first a wide range of managers from each division were summoned, and the emergency meeting participants confirmed the investigation procedures going forward as well as the timing and statements for the press release and product collection, on the assumption that a collection of the Product would be initiated and a press release issued in response to the detection of Peak X. Following this, a second emergency meeting concerning the Product was held from 5:00 p.m. on Monday, March 18 (separate from the emergency meeting concerning the Product held at 2:00 p.m.) in which employees falling below the Group Manager level from each department also participated. At this separate emergency meeting, the participants discussed and considered concrete actions regarding how to proceed with the investigation, the timing of the press release and product collection, sorting the risk matters aimed at the press release, and preparations for statements and a Q&A.[59]

[59] From between 5:00 p.m. and 7:00 p.m. on Monday, March 18, the persons in charge in the Pharmacovigilance Group and the R&D Group in the Central R&D Laboratory held an interview, which had been previously scheduled, with Medical Doctor S of a hospital affiliated with a national university in Japan, with attorney and medical doctor P in attendance. Medical Doctor S expressed an opinion that Cases 1, 3, and 4 were "Probable," while Case 5 was "Definite." In addition, Medical Doctor S indicated to the effect that even if a renal biopsy (generally meaning a medical procedure in which tissue is taken from the kidney and undergoes testing) had been taken, it would still be difficult to discern whether the cause in each case had been a toxicity (derived from the red yest rice, a mycotoxin, heavy metals, residual pesticides, or the like) or an allergic reaction caused due to the

3.9.3 Status of Discussions, Etc. in the Mar. 19 GOM

On Tuesday, March 19, the regular GOM was held (the "**Mar. 19 GOM**"). At the Mar. 19 GOM, although the results of the Mar. 13 External Expert Consultation and the interview with Medical Doctor S that was held on Monday, March 18 were reported, the main theme was that Peak X was detected and the response in accordance therewith. Namely, at the Mar. 19 GOM, it was reported that Peak X was detected both in the Product and also in the red yeast rice ingredients used in the Product, and the participants confirmed the plans for halting the shipment of the Product, conducting a product collection, and issuing a press release to that effect. In addition, at the Mar. 19 GOM, because there were opinions expressed to the effect that a certain amount of time would be required for preparing the call center, contacting suppliers, and the like in order to prevent consumer and supplier confusion, the timing of the halting the shipment of the Product, conducting a product collection, and issuing a press release was set for 3:00 p.m. on Tuesday, March 26.

In addition, because Senior Executive Director Yamane felt that the opinions expressed at the Mar. 13 External Expert Consultation had been insufficient, he instructed the General Manager of the Legal and Intellectual Property Department (the "**Legal and Intellectual Property Department**") of the Sustainability Management Headquarters to obtain advice from different attorneys. In response to this, on Tuesday, March 19, the Legal Group Supervisor in the Legal and Intellectual Property Department, held online interviews with and received advice from attorneys at multiple law firms, including MHM, and received advice therefrom by email after these online interviews. The Legal and Intellectual Property Department compiled a series of the content of the advice from those attorneys in the form of reference materials, which were given at the extraordinary meeting of the BOD on Friday, March 22.

Following the Mar. 19 GOM, daily emergency meetings were also held, at which employees of various divisions falling below the Group Manager level also participated. The participants at these emergency meetings discussed and considered concrete actions regarding the content of the statements for the press release and product collection, the timing of the reporting to governmental authorities, sorting the risk matters aimed at the press release, and preparations for statements and a Q&A.

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consumer's bodily constitution, and that supposing that the cause were a toxicity then it was strange that there were not many more victims.

3.9.4 Report to Outside Officers

Just before 12:00 p.m. on Tuesday, March 19, the General Affairs Department General Manager received an email from Senior Executive Director Yamane which instructed the General Affairs Department General Manager to prudently give an explanation to and make arrangements regarding the Issue with the Outside Officers and for the General Affairs Department General Manager to consult with the Senior General Manager of the Pharmacovigilance & Consumer Relations Division with respect to the content and timing of the explanation to the Outside Officers. Based on the subsequent progression of the discussions within Kobayashi Pharmaceutical, on the evening of Wednesday, March 20, the General Affairs Department General Manager reported to the Outside Officers by email that (i) it was discovered that a substance not included in the normal process for the red yeast rice ingredients of the Product was mixed, (ii) what such substance was, how the substance came to be mixed in and the cause thereof, and other factors had not yet been identified, (iii) there had been several patients who had developed kidney problems after ingesting the Product (however, for the time being, while there were cases in which patients had undergone dialytic treatment, there had been no cases of patient deaths), (iv) a plan to implement a collection of the product and issue a press release was decided at the Mar. 19 GOM, and (v) reporting to governmental authorities was scheduled on or after Thursday, March 21 and the press release was scheduled to be issued on Tuesday, March 26, respectively. The General Affairs Department General Manager additionally reported in that email on the expected impact on Kobayashi Pharmaceutical's business results that could accompany the collection of the Product and other related matters.

3.10 Report to Governmental Authorities, Press Release, and Product Collection

3.10.1 Report to Governmental Authorities

On the evening of Thursday, March 21, the person in charge of Foods with Functional Claims in the Domestic Quality Assurance Group called the Consumer Affairs Agency and reported to the effect that they would like to make a health issue report, and as a result of schedule arrangements with the Consumer Affairs Agency, Friday, March 22 was set as the date for an interview. In addition, the Consumer Affairs Agency instructed contact to the Osaka City Health Center.

On the morning of Friday, March 22, the Pharmacovigilance Group Manager and two other persons in charge brought a document in the name of the persons in charge of the

Pharmacovigilance Group titled “Report on Health Damage related to Foods with Functional Claims” to the Eastern Public Health Surveillance Branch Office of the Osaka Health and Welfare Center, where they reported since January, there had been multiple communications regarding kidney problems concerning the Product, which were foods with functional claims and were interviewed thereof.

In addition, at 3:15 p.m. on Friday, March 22, the General Manager of the New Product and Business Development Department in the Central R&D Laboratory, the Pharmacovigilance Group Manager, the Food R&D Group Manager, and three other persons in charge conducted an online meeting with the Consumer Affairs Agency (with the Ministry of Health, Labour and Welfare also in attendance). The participants from Kobayashi Pharmaceutical reported that there had been multiple communications since the start of 2024 regarding kidney problems concerning the Product and that Kobayashi Pharmaceutical would issue a press release that day on the implementation of a product collection.

3.10.2 Considerations on the Date and Time for Issuing the Press Release and the Lots Subject to the Collection

As stated in 3.9.3 above, at the Mar. 19 GOM, the timing of halting the shipment of the Product, the product collection, and the press release was set for 3:00 p.m. on Tuesday, March 26. However, there were also strong opinions, including from Chairman & CEO Kobayashi and Senior Executive Director Yamane, that the press release should be issued as early as possible; in particular, following the Mar. 18 BRM, Senior Executive Director Yamane had internally given instructions and urging for an early press release. Then, ultimately in consideration of the opinions of the attorneys at multiple law firms, including MHM, as stated in 3.9.3,[60] at a meeting held at 10:00 a.m. on Friday, March 22, at which Chairman & CEO Kobayashi, Senior Executive Director Yamane, and others participated, all meeting participants reached a consensus and decided on plans to (i) push forward the time of convening the extraordinary meeting of the BOD to 4:00 p.m. on Friday, March 22, (ii) issue the press release at 5:00 p.m. that day, and (iii) hold a press

[60] In parallel with these discussions and consultations with the attorneys through the Legal and Intellectual Property Department as stated in 3.9.3 above, around 1:00 p.m. on Thursday, March 21, Senior Executive Director Yamane also obtained the opinion of an attorney at a separate law firm. Said attorney’s opinion was that the issuance of a press release announcing product collection should be brought forward to the afternoon of Friday, March 22. As stated herein, Senior Executive Director Yamane himself was of the opinion that the press release should be made public on Friday, March 22, and he consulted with the attorney thereon for the purpose of confirming whether his thinking on the matter was correct.

conference after issuing the press release.

3.10.3 Issuance of Press Release (Announcement of Product Collection) and Holding of Press Conference

In response to the meeting held at 10:00 a.m. on Friday, March 22 as stated in 3.10.2 above, at 4:00 p.m. that day, the Extraordinary Meeting of the BOD for the 107th Term was held. At this meeting, the BOD resolved to officially decide on the collection of the Product and to issue the press release that same day.

At 5:00 p.m. on Friday, March 22, immediately following the extraordinary meeting of the BOD, a press release titled “Request for discontinuation of use of Red Yeast Rice related products and notice of voluntary collection” was posted on the website of Kobayashi Pharmaceutical. A press conference was then held from 6:00 p.m. that day in Osaka City. President & COO Kobayashi, the Senior General Manager of the Pharmacovigilance & Consumer Relations Division, the Senior General Manager of the Manufacturing Headquarters, and the Food Department Head attended the press conference and responded to questions.

4 Internal Control System and Quality Control System

4.1 Matters Investigated and Verified in this Report

The BOD has requested the Committee to investigate and verify the following matters: "an investigation into the factual events that took place after the cases were reported" and "a careful examination of the internal control system and quality control system of Kobayashi Pharmaceutical." However, it is neither realistic nor effective for the Committee to carefully examine and analyze, including from medical and pharmacological perspectives, every internal control system and quality control system at Kobayashi Pharmaceutical, taking into consideration the purpose of the request, expertise of the Committee, and speediness of the investigation.

Therefore, after deliberating this point with the Outside Directors, the Committee has decided to focus on the internal control system and quality control system in emergencies, which is closely related to "an investigation into the factual events that took place after the cases were reported," in light of the Committee's core responsibility to conduct fact-finding that will form the foundation of the BOD's subsequent verification.

Specifically, the Committee focused on the following facts: (i) what kind of internal systems had been established during ordinary operations at Kobayashi Pharmaceutical in preparation for cases of serious health damage and (ii) how the internal systems had actually functioned in an emergency such as this matter.

In this regard, in order to analyze the true cause of this matter and to implement effective measures for preventing recurrence, Kobayashi Pharmaceutical will be required to investigate and verify the appropriateness of its internal control system and quality control system in a broader sense. Therefore, the Committee expects the executives at Kobayashi Pharmaceutical to conduct serious investigation and verification of these matters under the supervision of the BOD, led by the Outside Directors, especially from the perspective of preventing future recurrence.

4.2 Facts Related to the Causes Requiring More Than Two Months for the Publication of the Issue

The Products are so-called health food products, and health food products are strictly "food products," which greatly depend on the assumption that ingesting such food products should not cause any health damage to consumers. Therefore, it is indisputable that the highest priority in manufacturing and selling health food products is food safety.

From this perspective, when carefully examining Kobayashi Pharmaceutical's internal control system and quality control system in the event of emergencies, based on the factual background up to the public announcement of the Issue outlined in 3 above, the Committee points out, in this 4.2, the facts related to the causes requiring more than two months for Kobayashi Pharmaceutical from the receipt of the report of Case 1 on Monday, January 15 to issue the Press Release on Friday, March 22. In addition, based on the causes requiring more than two months to publicly announce the Issue as pointed out in this 4.2, the matters that the Committee points out regarding Kobayashi Pharmaceutical's internal control system and quality control system in the event of emergencies are summarized in 4.3 below.

4.2.1 Awareness about Safety of Health Food Products (Sensitivity to Suspected Health Damage Caused by Health Food Products)

4.2.1.1 Kobayashi Pharmaceutical's Awareness about Safety of Health Food Products

As stated in 3 above, on Monday, January 15, the Customer Relations Office of Kobayashi Pharmaceutical was contacted by Medical Doctor A to the effect that a patient who had been ingesting the Product was hospitalized with a diagnosis of acute kidney failure at the hospital at which Medical Doctor A works after the patient showed a deterioration in health condition approximately two weeks after the patient ingested the Product and was undergoing dialysis treatment (Case 1). In addition, on Thursday, February 1, the Customer Relations Office of Kobayashi Pharmaceutical received a report from Medical Doctor B to the effect that three cases of a unique case known as tubulointerstitial nephritis, of which there are only three to four cases per year at the hospital at which Medical Doctor B works, had occurred in the last one to two months, and all of the three patients had ingested the Product (Cases 3 to 5). Upon Medical Doctor B making contact as stated above, Medical Doctor B also advised that it would be recommended to alert consumers about the possibility of developing tubulointerstitial nephritis. Kobayashi Pharmaceutical had never received any such specific reports of cases from medical doctors regarding serious health damage like the reports of Case 1 and Cases 3 to 5, with respect to the health food products that Kobayashi Pharmaceutical sold, including the Products, until Kobayashi Pharmaceutical received the reports of Case 1 and Cases 3 to 5.

Health damage should never occur as a result of ingesting health food products, and if

Kobayashi Pharmaceutical had received reports of cases like those stated above, even if the causal relationship was unclear, consumers, including those who intend to ingest the Products, would expect to be informed of the occurrence of such cases first of all, and they would also Kobayashi Pharmaceutical to immediately consider and implement effective measures to prevent the spread of such health damage, with the suspicion that there is a possibility of serious health problems resulting from the ingestion of the Products.

However, Kobayashi Pharmaceutical lacked this awareness, and when they received the reports of cases regarding serious health damage, they failed to prioritize the safety of the consumers ingesting health food products. As a result, Kobayashi Pharmaceutical's responses to the Issue was as set out in 4.2.1.2 and below.

4.2.1.2 Failure to Provide Information to Consumers

As stated in 4.2.1.1, over the two weeks from Monday, January 15 to Thursday, February 1, Kobayashi Pharmaceutical received reports on four cases of kidney problems from medical doctors. Moreover, Kobayashi Pharmaceutical was also advised by Medical Doctor B from Hospital β that it would be recommended to alert consumers that there was a possibility of developing tubulointerstitial nephritis.

However, Kobayashi Pharmaceutical had not immediately considered providing consumers with information on Case 1 and Cases 3 to 5 after receiving the reports of Case 1 and Cases 3 to 5. In addition, although Kobayashi Pharmaceutical temporarily considered the above-mentioned advice from Medical Doctor B partly because Medical Doctor B suggested that certain additional information be added to the "precautions for ingestion" of the Product at the Feb. 22 Medical Doctor Interview, the suggestion was not adopted, and in the end, Kobayashi Pharmaceutical did not alert consumers.

4.2.1.3 The Interpretation that Reporting to Governmental Authorities is Required "Only When the Causal Relationship Is Clear"

As stated in 4.2.3 below, Kobayashi Pharmaceutical had adopted the interpretation that, if health damage occurs to a person who ingested Foods with Function Claims such as the Product, reporting to governmental authorities is required "only when the causal relationship is clear" (the "**Interpretation**"), and did not report to the governmental authorities even at the stage of the receipt of the report of Cases 3 to 5 following Case 1.

In this regard, no one had stated that, as long as there was a suspicion that there would

be a possibility of the Cases resulted from the Products, effective measures should be considered and implemented to prevent the spread of the health damages, even though it was unclear whether or not the health damages resulted from the Products.

4.2.1.4 Timing of the Arrangement and Implementation of Medical Doctor Interviews Regarding Cases 1 and Cases 3 to 5

After Kobayashi Pharmaceutical received the reports from Medical Doctor A and Medical Doctor B regarding Case 1 and Cases 3 to 5, it also took some time for Kobayashi Pharmaceutical to conduct the detailed investigation through the interviews with these medical doctors.

More specifically, as stated in 3.7 above, Kobayashi Pharmaceutical sent an email to Medical Doctor B to arrange an interview therewith on Thursday, February 15, when two weeks had elapsed since it received the case report, and Kobayashi Pharmaceutical actually conducted an interview with Medical Doctor B on Thursday, February 22, when three weeks had elapsed since it received the case report. In addition, Kobayashi Pharmaceutical sent an email to Medical Doctor A to arrange an interview therewith on Thursday, February 8, when three weeks had elapsed since it received the case report, and Kobayashi Pharmaceutical actually conducted an interview with Medical Doctor A on Thursday, February 29 when a month and a half had elapsed since it received the case report.

4.2.1.5 Increase in the Number of Case Reports and Timing of Collection Decision, Etc.

Following the four cases of Case 1 and Cases 3 to 5, there were a growing number of reports of cases including acute kidney failure suspected to be related to the Products, and as of Thursday, March 7, the total number of cases including acute kidney failure cases suspected to be related to the Products had increased to a total of 13 (total of five reports from medical doctors and total of eight reports from consumers) (see Attachment 3.1).

However, as stated in 3.9 and 3.10 above, Kobayashi Pharmaceutical ultimately decided to report to the governmental authorities and conduct the collection of the Products on Friday, March 15, after Peak X was detected in specific product lots and ingredient lots of the Products.

4.2.2 Status of GOM Functions

4.2.2.1 Status of GOM Discussions

After Thursday, February 1, on which Kobayashi Pharmaceutical received the report of Cases 3 to 5, following Case 1, the Pharmacovigilance Department, the Food Department, and the Central R&D Laboratory had been leading the investigation to determine the cause of the Cases. At the weekly GOMs, the Pharmacovigilance & Consumer Relations Division and the Food Department provided specific explanations about the status of the investigation to determine the cause and future actions. The Issue was positioned as an item for deliberation at the GOMs, and continued to be carefully examined along with other agenda items, and the Pharmacovigilance Department, the Food Department, and other divisions had prepared detailed presentation materials each time and provided explanations at each GOM. Such explanations at the GOMs were provided a total of six times, once a week, from Tuesday, February 13 to Tuesday, March 19, until the Press Release was issued on Friday, March 22 (the GOMs held from Tuesday, February 13 to Tuesday, March 19 are collectively referred to as the "**Feb. 13 to Mar. 19 GOMs**").

At the Feb. 13 to Mar. 19 GOMs, the discussions regarding the Issue were primarily centered around the explanations provided by the Pharmacovigilance Department, the Food Department, and other divisions. With respect to the content of the discussions regarding the Issue at the Feb. 13 to Mar. 19 GOMs, at the suggestion of the Senior General Manager of Pharmacovigilance & Consumer Relations Division, no video recordings nor minutes were made since the Feb. 20 GOM. For this reason, the specific content of the discussions can only rely on the interviews conducted by the Committee, and in those interviews, some people stated that, at the Feb. 13 to Mar. 19 GOMs, although all of the Issues were treated as matters for deliberation (Article 8 of the Regulations for GOM), in fact, it was more like receiving reports rather than having discussions, and others stated that they did not remember any substantive discussions by the participants in the Feb. 13 to Mar. 19 GOMs taking place until the Mar. 19 GOM held for the first time after Peak X was detected, and it can be gathered that there were no proactive suggestions made by the participants in the Feb. 13 to Mar. 19 GOMs in response to the reports regarding the Issue given by the Pharmacovigilance Department, the Food Department, and other divisions.

4.2.2.2 Instructions for Ensuring Food Safety at the GOMs

Since the Feb. 13 GOM, the Interpretation that a report to the governmental authorities in case health damage occurs to a person who ingested Foods with Function Claims is required "only when the causal relationship is clear" was clearly stated in the materials for the Feb. 13 to Mar. 19 GOMs.

There were no objections to the Interpretation from any of the participants in the Feb. 13 to Mar. 19 GOMs. As a result, no one among the participants in the Feb. 13 to Mar. 19 GOMs made suggestions or gave instructions to report to the governmental authorities and to consider and implement effective measures to prevent the spread of health damage and protect consumers even if a "clear causal relationship" between the Products and each case is not clear.

In addition, President & COO Kobayashi, who attended all six Feb. 13 to Mar. 19 GOMs, had not taken the initiative in determining or giving instructions to put into action countermeasures such as a product collection and an alert to consumers to ensure food safety and had not made such determination or given such instructions outside the Feb. 13 to Mar. 19 GOMs, before Peak X was detected on Friday, March 15.

Moreover, Chairman & CEO Kobayashi, who has the same representative right as President & COO Kobayashi and did not attend the Feb. 13 to Mar. 19 GOMs, made suggestions to the Pharmacovigilance & Consumer Relations Division immediate responses that it would be better to suspend advertising for the time being and reduce the amount of monacolin K. However, Chairman & CEO Kobayashi had not taken the initiative either in determining or giving instructions to put into action countermeasures such as a product collection and an alert to consumers before Peak X was detected on Friday, March 15.

4.2.2.3 Statements in the Materials for the Feb. 13 to Mar. 19 GOMs Related to Sales, Advertising, Etc. of the Products

After the Feb. 13 GOM, the materials for the Feb. 13 to Mar. 19 GOMs contained information on the status of the sales and profits of the Products as well as the advertising and promotion of competitors' products. In addition, the Feb. 20 GOM materials indicated a plan as of that time of continuing measures regarding strengthened in-store sales such as revising advertising and increasing advertising expenses in order to improve the sales of the Products. Furthermore, the Mar. 12 GOM materials stated the plan to suspend advertising for the Products upon the addition of two more cases of hospitalization based

on the consultation with external experts on March 6, but it also stated the amount of impact on sales that would be caused by suspending advertising. Further, as stated in 2.5.1 above, sales of the red yeast rice related business had been growing steadily particularly in the B-to C Business, and been on an upward trend.

Moreover, after the Feb. 26 GOM materials, as a factor to take into account when considering the necessity of reporting to governmental authorities, the materials for the Feb. 13 to Mar. 19 GOMs included the statement of not only "discussing with attorneys and experts, carefully examining the causal relationship and seriousness from both medical and pharmacological perspectives" but also "taking into account the reputational risk and impact on the business."

In this regard, as stated in 3.5.3 above, there are no video recordings or minutes of the GOMs after Tuesday, February 20, and the Committee's investigation did not find any fact that there were discussions in a tone that it was acceptable to disregard food safety in order to maintain the red yeast rice business. However, in light of the above statements in the materials for the Feb. 13 to Mar. 19 GOMs, it can be gathered that Kobayashi Pharmaceutical responded to the Issue with a certain degree of awareness of maintaining the red yeast rice business.

4.2.3 The Interpretation that Report to Governmental Authorities is Required "Only When the Causal Relationship Is Clear"

4.2.3.1 Interpretation of "Risk of Occurrence and Spread of Health Damage"

Kobayashi Pharmaceutical had adopted the Interpretation that, if health damage occurs to a person who ingested Foods with Function Claims such as the Product, reporting to governmental authorities is required "only when the causal relationship is clear." While there is no statement in the administrative documents introduced below that provides a direct basis for the Interpretation that reporting to governmental authorities is required "only when the causal relationship is clear," the Pharmacovigilance Department had adopted this interpretation as its criteria for reporting to governmental authorities from around 2020, prior to the occurrence of the Issue.

That is to say, the criteria for reporting health damage regarding Foods with Function Claims to the Consumer Affairs Agency is set out in "3. Reporting to the Consumer Affairs Agency" under Section 2 of "IV. (IV) Matters related to collection of information on health damage" in the Notification Guidelines, which states that "the notifier shall promptly report to the Food Labeling Planning Division of the Consumer Affairs Agency

if, as a result of the evaluation, there is a risk of occurrence and spread of health damage due to the notified food" (emphasis added). While Kobayashi Pharmaceutical interpreted this provision to mean that reporting is required when both requirements of "occurrence of health damage due to the notified food" and "risk of spread of such health damage" are met, Kobayashi Pharmaceutical also believed that the Notification Guidelines were not clear as to when the former requirement of "occurrence of health damage due to the notified food" should be determined to have been met.

Hence, the Pharmacovigilance Department of Kobayashi Pharmaceutical referred to the "Guidelines for Handling and Guidance on Foods for Specified Health Uses (Revised on November 13, 2023) (CFL Notification No. 669)." That is to say, these guidelines stipulate that the situations in which reporting to governmental authorities of health damage is necessary is when "the person who have received approval etc. for Foods for Specified Health Uses obtains knowledge indicating that there is a risk of death or serious illness among the harms resulting from the food in question." The Pharmacovigilance Department interpreted the wording "resulting from" in the provision to mean that "the causal relationship is clear," and adopted the Interpretation that, if health damage occurs to a person who ingested Foods with Function Claims, reporting to governmental authorities is required "only when the causal relationship is clear." In adopting the Interpretation, the Pharmacovigilance Department did not consult with any governmental authority or attorney etc. regarding the Interpretation.

However, at the beginning of "IV. (IV) Matters related to collection of information on health damage" in the Notification Guidelines, it is stated that "unlike pharmaceutical products, there is no limitation on the ingestion of Foods with Function Claims; therefore, if any health damage occurs, there is a risk that the occurrence will spread rapidly. Thus, it is appropriate to report promptly even if the information obtained is insufficient." In addition, in the "Q&A on Foods for Specified Health Uses" released by the Consumer Affairs Agency regarding "Permission for Labeling of Foods for Specified Health Uses," the answer to Question No. 69 "What does 'knowledge indicating that there is a risk of death or serious illness among the harms resulting from the food in question' refer to?" is also given as "the knowledge of the occurrence or high probability of the occurrence of serious illness, including death, due to the ingestion of the food in question or the functional substance." In any case, there is no statement that provides a direct basis for the Interpretation that, if health damage occurs to a person who ingested Foods with Function Claims, reporting to governmental authorities is required "only when the causal relationship is clear."

4.2.3.2 Kobayashi Pharmaceutical's Response Based on the Interpretation

The Interpretation by Kobayashi Pharmaceutical (i.e., if health damage occurs to a person who ingested Foods with Function Claims, reporting to governmental authorities is required "only when the causal relationship is clear") had been stated since the materials for the Feb. 13 GOM that first addressed the Issue. The Pharmacovigilance & Consumer Relations Division provided an explanation on the Interpretation at the Feb. 26 GOM, while, until then, the Interpretation had only been stated in GOM materials and no particular explanation had been provided. However, as stated in 4.2.2.2 above, the participants of the GOM made no objections to the Interpretation. In addition, it was not confirmed that there was any fact that the Pharmacovigilance & Consumer Relations Division had reverified whether the Interpretation was correct prior to explaining the Interpretation at the Feb. 13 to Mar. 19 GOMs.

As a result, despite receiving the report on Case 1 from Medical Doctor A on Monday, January 15, the reports on Cases 3 to 5 from Medical Doctor B on Thursday, February 1, and subsequent reports on multiple cases including acute kidney failure as stated in Attachment 3.1, Kobayashi Pharmaceutical continued to only investigate the scientific causes of the Cases and did not conduct reporting to governmental authorities or product collection.

Since Kobayashi Pharmaceutical believed that reporting to governmental authorities would be conducted in conjunction with a product collection, it did not adopt the idea of only conducting reporting to governmental authorities or seeking administrative counseling prior to making a decision to conduct a product collection.

4.2.4 Investigation of Contamination by Other Ingredients in the Manufacturing Process

4.2.4.1 Establishment of Hypotheses concerning Health Damage

Kobayashi Pharmaceutical began marketing the predecessor of the Product, "Beni-koji Choletol," in May 2018, and began marketing the Product as a Food with Function Claims in April 2021. However, Kobayashi Pharmaceutical had never received any reports of serious health issues such as acute kidney failure, including the time during when "Beni-koji Choletol" was on the market, until Case 1 was reported.

In response to the reports of Case 1 and Cases 3 to 5, Kobayashi Pharmaceutical, at the

Feb. 5 Ad-hoc Meeting, as described in 3.4.1 above, formulated three hypotheses as the cause of the Cases: (i) possibly caused by citrinin, (ii) possibly caused by coincidental ingestion by persons who react to statins including monacolin K, a valuable ingredient in the Product, and (iii) possibly caused by the effect of, or the contamination by, other ingredients.

4.2.4.2 Exclusion of the Possibility regarding the Effect of, or Contamination by Other Ingredients from Priority Consideration

In order to verify those hypotheses, Kobayashi Pharmaceutical commissioned an outside contractor to conduct tests as stated above in 3.5.2 to confirm whether the Cases were (i) possibly caused by citrinin, and confirmed that the Products were not contaminated by citrinin. As for the hypothesis in which the Cases have been (ii) possibly caused by coincidental ingestion by persons who react to statins including monacolin K, a valuable ingredient in the Products, as stated above in 3.4.3, Kobayashi Pharmaceutical conducted a literature search on monacolin K in the Products and confirmed the amount of the ingredients etc., and as stated above in 3.5.3, considered in to setting the upper limit of the amount of monacolin K in the Products etc., and in addition, as stated above in 3.7, sought opinions on the possibility of rhabdomyolysis in the interviews with the medical doctors who reported the Cases to Kobayashi Pharmaceutical.

On the other hand, on Monday, February 5, in order to investigate whether the Cases were (iii) possibly caused by the effect of, or the contamination by, other ingredients, Kobayashi Pharmaceutical requested a member of the Meitanhompo Quality Management Group to confirm whether or not there had been any changes in the rice and rice germ, which were the raw ingredients of the red rice yeast used in the Products, and the manufacturing process thereof, in 2023 at the Osaka Plant. The requested confirmation regarding changes in the manufacturing process were to confirm whether or not there had been any changes in manufacturing conditions or changes in personnel, and did not include confirmation of whether or not there had been any incidents such as equipment failure. Kobayashi Pharmaceutical was informed by that member that no particular changes were found. In parallel, Kobayashi Pharmaceutical also confirmed whether there had been any changes in raw ingredients with the contractor, and was informed that no particular changes were found. As a result, the possibility of the effect of, or the contamination by, other ingredients was determined to be low, and the possibility of the effect of, or the contamination by, other ingredients was not made a priority consideration.

Subsequently, as stated above in 3.7.1, following the Feb. 22 Medical Doctor Interview, the possibility that some toxic substance had been produced or mixed in the products came to be suspected, and preparations for the necessary tests were undertaken, however, until it was pointed out by attorney and medical doctor P, in the Mar. 6 External Expert Consultation that a product lot manufactured during a specific time might have been the cause of the Issue, there was not a focus on identifying the product lots that the Case patients ingested, and even compared to other hypotheses, there was insufficient awareness of the risk of contamination at the manufacturing stage with a focus on individual lots.

After receiving the above-mentioned advice from attorney and medical doctor P, Kobayashi Pharmaceutical again attempted to identify the product lots that were believed to have been ingested by the case patients. As a result, Kobayashi Pharmaceutical realized that the product lots that were believed to have been ingested by the case patients had some points in common and decided to conduct HPLC analysis of the product lots, and on Friday, March 15, Peak X was detected.

4.2.4.3 Facts Related to the Possible Effect of, or Contamination by Other Ingredients

At the Osaka Plant, there were three groups: the Production Group, the Quality Management Group, and the Management Group. And one of the three lines in the Production Group was the production line for red yeast rice raw ingredients, with about five to six employees in charge of manufacturing at the site. However, the work, including quality control of red yeast rice raw ingredients, had been almost entirely entrusted to the personnel belonging to the Quality Management Group and other employees only supported a part of the personnel's work. This situation was the same at the Kinokawa Plant, to which the manufacturing line including manufacturing equipment for red yeast rice raw ingredients was transferred. The said personnel in charge of quality management reported to the said personnel's direct supervisor, the Quality Management Group Manager, only when there was something wrong, and reported to the supervisor above the said personnel's direct supervisor, the President and Plant Manager of Meitanhompo, only when there was a major problem.

In addition, despite the fact that the production capacity of red yeast rice raw ingredients had been enhanced as stated above in 2.5.1, the operations, including the quality management of the manufacturing line which included the manufacturing facilities for red yeast rice raw ingredients, had been almost entirely left to personnel on

site, and staff shortages had become the norm.

Further, with regard to the Osaka Plant, although it is unclear whether or not the following were the cause of the Issue, the following points were mentioned in the interviews conducted by the Committee (i) at the time of manufacture of the lot of raw ingredients used for the Products at issue (the beginning of November 2022), the dryer broke down during the drying process and the red yeast rice bacteria in the said lot was left undried for a certain period of time; (ii) blue mold had adhered to the inside of the cover of the tank used to culture red yeast rice, and the personnel in charge of quality control, who had been told of the aforesaid, said that, on occasion, blue mold is mixed in to some extent; (iii) when the red yeast rice production line was transferred from the Osaka Plant to the Kinokawa Plant, the exhaust ducts, which were a part of the drying process equipment in the production, were found to have been clogged at the deepest part, and might not have been exhausting properly up until then.

However, after becoming aware of the Issue and during the period up until the Press Release on Friday, March 22, Kobayashi Pharmaceutical made no proactive attempts to ascertain the actual circumstances of manufacturing by directly asking the personnel in charge of manufacturing about issues in the manufacturing process, etc.

4.3 Matters Pointed out Regarding the Internal Control System and Quality Control System for Emergencies

4.3.1 Insufficiency in Crisis Management Awareness

4.3.1.1 Lack of Effectiveness of the Feb. 13 to Mar. 19 GOMs

As stated in 4.2.2 above, Kobayashi Pharmaceutical had conducted a company-wide review of the Issue at the Feb. 13 to Mar. 19 GOMs. Then, as stated in 2.3.4 above, the members of the GOM consisted of Inside Directors, Executive Officers, and Full-Time Audit and Supervisory Board Members, excluding Chairman & CEO Kobayashi, and with regard to the Feb. 13 to Mar. 19 GOMs, numerous persons involved in the analysis of the Issue, were also present. Therefore, in light of the composition of the meeting body, it cannot be said that the fact that the GOM discussed and examined the policy on the serious issue of health damage was a problem in and of itself.

However, since the Issue was positioned as a “Discussion Item” (Article 8.1 of the Regulations) among the supplementary agenda items in the Regulations for GOM, the related materials were basically sent immediately before the GOM, or in some cases, the

attendees saw them for the first time at the GOM where they were projected on the screen.[61] Therefore, it was difficult for the attendees of the Feb. 13 to Mar. 19 GOMs to carefully read the materials on the Issue before attending those GOM.

In addition, the GOM was held about once a week, and up until Peak X was detected, the scheduled length of time for the discussions on the Issue was generally 15 to 20 minutes,[62] and in addition to the Issue, there were fourteen items at the most, and four items at least, on the agenda for the deliberation and the reporting alone. Therefore, it was difficult for the GOM to discuss and examine the Issue in an in-depth manner with sufficient time.

Furthermore, although the Regulations for GOM stipulate that resolutions of the GOM shall be approved by the President (Article 10.1 of the Regulations), President & COO Kobayashi did not take the initiative in the GOM to make decisions to collect products and provide an alert to consumers in order to ensure the safety of consumers.

As a result, at the GOM, basically the current status and future plans were reported and the plans were merely confirmed, in accordance with the materials prepared by the Food Department and the Pharmacovigilance Department, etc., and it is difficult to say that sufficient consideration and effective discussion were promptly conducted.[63]

4.3.1.2 Non-Establishment of a Crisis Management Headquarters

Kobayashi Pharmaceutical's Crisis Management Regulations stipulate that a Crisis Management Headquarters will be established "when a serious product accident or a large-scale collection is expected to occur." Therefore, it is believed that a Crisis Management Headquarters could have been established to deal with the Issue as well.

To be more specific, the Crisis Management Regulations stipulate that, when "Crisis Management Information"[64] is obtained, a Crisis Management Headquarters[65] shall be

[61] The Regulations for GOM stipulate that "materials on matters to be discussed at the GOM shall be submitted to the Secretariat two business days prior to the date of the meeting, except for discussion items, and the Secretariat shall distribute them to each member in advance" (Article 9 of the Regulations).
[62] Only for the March 19 GOM, which was held after the detection of Peak X, the length of time was 35 minutes.
[63] At the BOD meeting held on February 21, the Outside Directors raised the issue, in general terms, that discussions the GOM were not in-depth and that the reasons for this needed to be analyzed.
[64] This includes "when cases where a serious product accident or a large-scale collection is expected to occur" (Crisis Management Guidelines I, (iii)) and "other cases where considerable damage has occurred or is expected to occur in terms of business management" (Crisis Management Guidelines I, (ix)).
[65] The duties of the Crisis Management Headquarters take precedence over its normal duties, and the Crisis Management Headquarters takes precedence in the chain of command (Article 10.2).

established under the determination of the President & COO, with the President & COO of Kobayashi Pharmaceutical as the General Manager and the Risk Management Department of the Sustainability Management Headquarters as the secretariat (Article 5 of the Regulations), and necessary measures shall be taken under these Headquarters. Moreover, the Crisis Management Headquarters shall have full authority to carry out its roles and functions with respect to such matters as it deems reasonable and appropriate (Article 9 of the Regulations).

Considering the content and seriousness of the Issue, it would have been better, in terms of the choice of organizational body, to apply the Crisis Management Regulations, establish a Crisis Management Headquarters based on the Regulations, and conduct intensive crisis management under the direct leadership of President & COO Kobayashi, than to discuss responses at the GOM, which meets once a week.[66] Leaving aside what difference this could have made in the actual conclusion of this matter, the fact that Kobayashi Pharmaceutical did not at least have the awareness to specifically consider the option of addressing the Issue as a special response under the Crisis Management Headquarters is questionable as a form of crisis management in an emergency, and if they had been doing so with such level of awareness, it is possible that they could have held intensive discussions on the Issue and taken prompt action.

4.3.1.3 Failure to Share Information with Outside Officers

As stated above in 2.3.2 and 2.3.3, the Outside Directors account for a majority of the BOD, and the Outside Audit and Supervisory Board Members also account for a majority of the Audit and Supervisory Board. Based on their experiences outside of Kobayashi Pharmaceutical, these Outside Officers were in a position to express their opinions from a different perspective (a perspective closer to consumers) than the executives and employees who were considering the issue in the GOM, and one of the Outside Audit and Supervisory Members was qualified as an attorney and was able to provide opinions from a legal perspective. Therefore, if the information on the Issue had been shared with the Outside Officers in a timely and close manner and appropriate issues had been raised, some useful opinions could have been obtained regarding the appropriateness of Kobayashi Pharmaceutical's responses as a crisis management.

In fact, however, information concerning the Issue was not shared with the Outside

[66] In fact, the Crisis Management Headquarters (referred to as the "Task Force" by Kobayashi Pharmaceutical), which was established after the Press Release, has been intensively discussing the policy and other matters concerning the Issue for consecutive days.

Officers in a timely manner. In this regard, as stated above in 3.7.5, at the Mar. 4 TEAM-F Meeting, Full-time Audit and Supervisory Board Member Kawanishi pointed out two actual cases including the Issue, and pointed out that, as a general matter, there were no internal rules regarding the sharing of risk information with Outside Directors at Kobayashi Pharmaceutical, and that matters concerning such decision-making were unclear, and therefore recommended that the procedures for sharing risk information with Outside Directors should be clarified, for example, by establishing certain standards. However, the information regarding the Issue was not shared with the Outside Directors until the evening of Wednesday, March 20, as stated in 3.9.4 above. In addition, as for the Outside Audit and Supervisory Board Members, Full-time Audit and Supervisory Board Members reported the Issue and some discussions were made thereon at the Feb. 21 Audit and Supervisory Board Meeting as stated in 3.6.2.2 above, however, the Outside Audit and Supervisory Board Members only discussed the Issue for slightly less than 10 minutes because the Outside Audit and Supervisory Board Members typically had to discuss about 15 to 20 monthly reports each month at the meetings. Thereafter, the information on the Issue was updated and shared with the Outside Audit and Supervisory Board Members on Wednesday, March 20, when one month had already passed since that Feb. 21 Audit and Supervisory Board Meeting. It is hard to say that such timing of information sharing was appropriate.

4.3.2 Confusion in Rules for Responding to External Parties and Interpretations in Cases of Health Damage (Especially When it is Unclear Whether the Damage was Caused by the Product)

4.3.2.1 Key Rules in Cases of Health Damage

As rules of Kobayashi Pharmaceutical that are believed that should have been referred to when responding to the Issue, there are the Flowchart from the Collection of Health Damage Information to the Implementation of Measures (the "**Reporting Flowchart**"), the Product Collection Rules, and the Flow for Determining Product Collections (the latter two are hereinafter collectively referred to as the "**Collection Rules**"). While the details of the Reporting Flowchart and the Collection Rules are described below, it is questionable whether the Pharmacovigilance & Consumer Relations Division accurately complied with these rules when responding to the Issue. As stated in 4.2.3 above, it can be considered that the Pharmacovigilance & Consumer Relations Division focused on determining the cause based on the Interpretation that reporting to governmental

authorities is required “only when the causal relationship is clear.”

First, the Reporting Flowchart is the flowchart actually notified by Kobayashi Pharmaceutical to the Consumer Affairs Agency pursuant to the requirement for food-related operators to notify the Consumer Affairs Agency in accordance with the Notification Guidelines. The Reporting Flowchart stipulates the overall flow of what procedures should be taken in response to matters related to Foods with Function Claims, from the collection of health damage information leading up to the implementation of various measures.

Second, the Product Collection Rules stipulate the flow for conducting product collections up to the completion of the response in the event that a product collection becomes necessary due to reasons related to its quality or other reasons (Articles 1 and 4 of the Product Collection Rules). In addition, the Flow for Determining Product Collections stipulates the flow for determining collections in which management decisions are made on whether a product collection is necessary due to reasons related to its quality or other reasons (Articles 1 and 5 of the Flow for Determining Product Collections), which can be understood to be used prior to the Product Collection Rules.

4.3.2.2 Inconsistency Between the Reporting Flowchart and the Collection Rules

However, an inconsistency may arise between the Reporting Flowchart and the Collection Rules when health damage occurs with respect to a product (Foods with Function Claims) and the causal relationship cannot be confirmed.

In other words, according to the Reporting Flowchart, if the answer to the question “Whether the adverse event caused by our product (including when the causal relationship is unclear)” is “Yes,” Kobayashi Pharmaceutical should evaluate the seriousness of the event, report to the Pharmacovigilance & Consumer Relations Division, decide on measures to be taken, and proceed to the “implementation of measures” (as such, “(including when the causal relationship is unclear)” is clearly written in the Reporting Flowchart). Further, since the “implementation of measures” includes the provision of information to consumers and prompt reporting to administrative agencies such as health centers and the Food Labeling Planning Division of the Consumer Affairs Agency, it would be natural for Kobayashi Pharmaceutical to provide information to consumers and report to administrative agencies even when the causal relationship between the product and health damage is unclear.

On the other hand, the Collection Rules make no reference to when the causal

relationship is unclear. Thus, it was the understanding of some personnel in the Pharmacovigilance & Consumer Relations Division that, based on the Interpretation, the Collection Rules stipulated procedures[67] for determining whether or not to conduct a collection based on the assumption that a causal relationship has been found between Kobayashi Pharmaceutical's product and the information on defects.[68] Setting aside the question of whether this understanding is correct, according to this understanding, since the causal relationship cannot be confirmed for the Issue, Kobayashi Pharmaceutical would not be required to conduct a product collection or reporting to governmental authorities under the Collection Rules.[69]

Therefore, if the understanding by the Pharmacovigilance & Consumer Relations Division above were to be adhered to, an inconsistency would arise between the Reporting Flowchart and the Collection Rules regarding the necessity of reporting to governmental authorities and product collections. With regard to this matter, there seems to have been confusion within Kobayashi Pharmaceutical, as some personnel stated that they responded with awareness of the Reporting Flowchart, while others stated that they understood that decisions should be made solely in accordance with the Collection Rules and they were not fully aware of the existence of the Reporting Flowchart.

In addition, as stated above, according to the Reporting Flowchart, prompt reporting to administrative agencies should be required even if the causal relationship is unclear. In other words, the Interpretation could not have been adopted if one followed the Reporting Flowchart. However, even those who stated that they responded with awareness of the

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[67] Further, the Flow for Determining Product Collections itself lacks rigor regarding the criteria for determining seriousness. For example, Chart 2 of the Flow for Determining Product Collections stipulates the following procedures: if there is any "risk of health damage" or "breach of law," or there are "any ethical issues," after which there is a "risk of spread," then a collection will be conducted. On the other hand, Article 7(1) of the Flow for Determining Product Collections stipulates the understanding that Kobayashi Pharmaceutical will consider its determination by referring to the following five factors: "risk of occurrence of health damage," "risk of breach of laws and regulations," "risk of reputational risk," "risk of spread to other products," and "whether the matter constitutes a collection (recall) of food products."

[68] According to the senior people at the Pharmacovigilance & Consumer Relations Division, all of the previous product collections they had experienced at Kobayashi Pharmaceutical were cases in which the causal relationship was clear.

[69] Further, as the Flow for Determining Product Collections was revised in December 2022, the current "Flow for Determining Food Collections (Chart 2)" in the Flow for Determining Product Collections is the revised version. The former chart equivalent to the "Flow for Determining Food Collections (Chart 2)" stipulated that, when there is "an occurrence or risk of occurrence of health damage," and (when there is a "risk of spread," then automatically but) if required as a result of responding to the issue individually even when there is no "risk of spread," Kobayashi Pharmaceutical will notify the authorities (mainly health centers), and that the notification to the authorities will be made prior to conducting a product collection or notifying distributors and consumers.

Reporting Flowchart had adopted the Interpretation that reporting to governmental authorities is required "only when the causal relationship is clear," and no reasonable explanation was obtained in the Investigation as to the relationship between the Interpretation and the Reporting Flowchart.

Therefore, it is considered that Kobayashi Pharmaceutical's internal rules and the interpretations thereof in the event that health damage occurs with respect to Foods with Function Claims had not been systematically established in terms of reporting to governmental authorities and product collections, resulting in the lack of promptness and smoothness in responding to the Issue.

4.3.3 Insufficiencies in Establishment and Operation of Information Sharing System

4.3.3.1 Insufficient Information Sharing with the GOM

For any report of cases received by the Customer Relations Office from a medical doctor or a consumer, Kobayashi Pharmaceutical had implemented an information management system called "FastHelp" to share the information of such cases within Kobayashi Pharmaceutical. But regarding the Issue, it is questionable whether specific information on each of the Cases recorded in the FastHelp was sufficiently shared with the GOM.[70]

Specifically, of the information recorded in FastHelp, the GOM materials contained basic and pro forma information such as the date on which the information was received, whether sold through OTC or direct marketing, information source (name of the medical institution or the consumer), sex, age, symptoms/diagnostic name/duration of use, and the lot number of the Products. Meanwhile, the GOM materials did not contain information on specific exchanges made between the Customer Relations Office and the medical doctors or the consumers (e.g., details of the symptoms and the statements made by medical doctors) until after the Feb. 22 Medical Doctor Interview.

As a result, it is possible that the gravity of the situation that the reports from medical doctors on Case 1 and Cases 3 to 5 received especially during the period from Monday, January 15 to Thursday, February 1, were different from the cases reported to the Customer Relations Office in the past had not been sufficiently communicated as first

[70] It is considered that the situation upon sharing such information through the Direct Marketing Department was basically the same.

hand information to the attendees of Feb. 13 to Mar. 19 GOMs.

4.3.3.2 Limitations on Information Sharing Using FastHelp

In accordance with the Customer Relations Regulations, the Customer Relations Office[71] recorded the "communications" it received from medical doctors and consumers on FastHelp and reported them to the Pharmacovigilance Department.

Specifically, a member of the Customer Relations Office, who received the report of Cases 3 to 5 from Medical Doctor B on Thursday, February 1 and was requested to confirm whether or not there was any information regarding tubulointerstitial nephritis, responded to Medical Doctor B after internal confirmation, that "there have been no reports of side effects of acute kidney failure to date." However, in fact, as of Monday, January 15, the Customer Relations Office received the report in relation to Case 1 from Medical Doctor A that a patient who had ingested the Product had acute kidney failure, and as of Wednesday, January 17, a member of the Pharmacovigilance Group also received a report that it had only been the Product that had a correlation in terms of time with kidney problems. These details had been recorded on FastHelp in a timely manner and had been also separately shared by email within the Pharmacovigilance Group. However, despite that, as stated above, the Customer Relations Office failed to inform Medical Doctor B of the fact that there had been another report of acute kidney failure.[72]

If this fact had been informed to Medical Doctor B, it is possible that Medical Doctor B would have raised even more serious issues, and it must be said that there were problems regarding the way information was shared within the Customer Relations Office which relied on FastHelp.[73]

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[71] The matters that are pointed out in this section may also apply to health damage information via the Direct Marketing Division and the Direct Marketing Department, but given that Case 1 and Cases 3 to 5, which occupy particularly important positions in the Issue, were all health damage information via the Customer Relations Office, the information in this section is focused on the Customer Relations Office.

[72] In relation to Case 1, the fact that Medical Doctor reported that a patient who had ingested the Product showed a deteriorated health condition approximately two weeks from the ingestion of the Product was not properly shared, and as a result, in the Feb. 29 Medical Doctor Interview, it was confirmed that the patient had only been ingesting the Product for a short period and that the patient had no concomitant medications or medical history, by which some were greatly impacted.

[73] FastHelp does not have a function to automatically notify persons when information is updated. For this reason, in order for persons other than updaters to promptly ascertain updated information on FastHelp after it is updated, the only way to check for updated information was to voluntarily access FastHelp at some point in time, or to access FastHelp and check for updates after being notified by the updater that it had been updated. There was no operational practice of each updater informing others each time after updating FastHelp to that effect, and even in the Issue, it can be considered that the

4.3.4 Failure of the Pharmacovigilance & Consumer Relations Division to Take Optimal Actions

4.3.4.1 Insufficient Checks-and-Balances by the Pharmacovigilance & Consumer Relations Division

The Pharmacovigilance & Consumer Relations Division had been cooperating with the Healthcare Products Headquarters and other divisions to respond to the Issue. For example, as stated in 4.2.2.1 above, the Pharmacovigilance Department had been analyzing the cause of the Issue not only within the Pharmacovigilance & Consumer Relations Division, but also by requesting cooperation from the Food Department that belongs to the Healthcare Products Headquarters.[74]

However, as stated in 2.4 above, the Pharmacovigilance & Consumer Relations Division is, in the first place, an organization established to endeavor to improve the quality assurance system, the pharmaceutical management system, and the pharmacovigilance system, and thereby to improve the reliability of Kobayashi Pharmaceutical Group as a whole. In other words, the Pharmacovigilance & Consumer Relations Division is expected to take a step back and act as a brake on the Headquarters whose goals are to promote business, from the perspectives of maintaining product quality and assuring safety. Despite this, for example, as stated in 4.2.2.3, the materials for the Feb. 13 to Mar. 19 GOMs contained the statements of "taking into account the reputational risk and impact on the business" as the factors to take into account when considering the necessity of reporting to governmental authorities, in addition to statements related to the status of the sales and profits of the Products as well as the advertising and promotion of competitors' products. From these statements, it can be gathered that the Pharmacovigilance & Consumer Relations Division was also aware that significant impact on business performance could not be avoided if Kobayashi Pharmaceutical were to make the decision to conduct reporting to governmental authorities and collection the Products.

It cannot be denied that, given that the Pharmacovigilance & Consumer Relations Division is also a part of Kobayashi Pharmaceutical, and in a broad sense, the Pharmacovigilance & Consumer Relations Division exists to pursue the interests of

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persons who have access to FastHelp would not have been aware of updated information unless they voluntarily check the updated information on FastHelp.

[74] In light of the seriousness of the Issue, such broad cooperation itself is considered a necessary aspect.

Kobayashi Pharmaceutical. However, from the perspective of Kobayashi Pharmaceutical's top priority of "ensuring safe and secure quality" as its quality assurance policy, it can be pointed out that, in respect to the responses to the Issue, the Pharmacovigilance & Consumer Relations Division failed to sufficiently apply the brakes in light of its responsibilities.

4.3.4.2 Insufficient Check Over the Pharmacovigilance & Consumer Relations Division's Policies

As stated in 4.2.2.1 above, the Pharmacovigilance & Consumer Relations Division played a leading role in considering the Issue, in cooperation with the Healthcare Products Headquarters and other departments. However, in retrospective, it is considered that there was insufficient check over the Pharmacovigilance & Consumer Relations Division.

For example, as stated in 4.2.3.1 above, the Interpretation that reporting to governmental authorities is required "only in cases where the causal relationship is clear," originated from the Pharmacovigilance Department's understanding of the Consumer Affairs Agency's "Guidelines on Notification of Foods with Function Claims" and "Guidelines for Handling and Guidance on Foods for Specified Health Uses." However, when making such an important interpretation, rather than leaving the matter solely to the Pharmacovigilance Department, it would have been appropriate for the Legal and Intellectual Property Department and other administrative departments to have been involved, and the matter to have been consulted with outside experts at an early stage as necessary, and if further required, directly inquired with the Consumer Affairs Agency.

However, Kobayashi Pharmaceutical did not take any such action on the Issue. As a result, Kobayashi Pharmaceutical relied on the policies of the Pharmacovigilance & Consumer Relations Division and did not carry out reporting to governmental authorities on the Issue nor collection the Product until Friday, March 22. The management team and senior people who attended the Feb. 13 to Mar. 19 GOMs should have had reasonable doubts about the policies of the Pharmacovigilance & Consumer Relations Division and exercised their oversight functions over the policies of the Pharmacovigilance & Consumer Relations Division, such as by using internal or external resources other than the Pharmacovigilance & Consumer Relations Division. However, as described in 4.3.1.1 above, the matters discussed at the Feb. 13 to Mar. 19 GOMs were basically limited to reports on the current status and future approach in accordance with the materials prepared by the Food Department and Pharmacovigilance Department and the attendees'

confirmation of these policies; therefore, it can hardly be said that sufficient consideration or effective discussion was conducted promptly at the meetings.

4.3.5 The Quality Management System was Left to the Field

As stated in 4.2.4.3, at the Osaka Plant and the Kinokawa Plant after the transfer, under the circumstances of labor shortage, the operations including the quality management of the manufacturing lines of the red yeast rice ingredients that were used for the Products almost entirely depended on the personnel in charge of such operations onsite. In regular operations, unless something wrong occurred, such personnel did not particularly share information with the said personnel's superiors including the plant manager.

In addition, there was no such situation that any division or department in the head office had accurately ascertained the actual conditions of the Osaka Plant and the Kinokawa Plant after the transfer by conducting on-site inspection or by other methods.

As such, it must be said that, in practice, part of the quality management of the Products was left to the personnel in charge of the operations on site, and there is room for improvement in the state of such quality management systems.

5 Summary Conclusion

The Committee investigated and carefully examined the matter commissioned by the BOD, and reports as stated in 1 to 4 above. While the BOD is scheduled to conduct a series of reviews regarding the Issue based on the Committee's findings, the Committee would like to provide a summary conclusion on the Issue.

Kobayashi Pharmaceutical received the first report of a case from a medical doctor in mid-January 2024, and received the report of three cases of kidney problems from a medical doctor of a different hospital on February 1. Kobayashi Pharmaceutical had never successively received such serious health damage reports concerning health products. In light of this, it can be said that, from the beginning of February at the latest, the entire company had been faced with an emergency in which it was strongly required to take a stance, whereby it gave the highest priority to the safety of the consumers who ingested the Products, with an emphasis on the steps of announcing the status of health damage and collecting the Products, immediately contacting doctors in charge who reported the cases of health damage and external experts (medical doctors and attorneys), and consulting with the governmental authorities and actively seeking their assistance. While investigation for the cause and causal relationship is important, in cases of food accidents in general, if too much focus is placed on investigating the cause and causal relationship, it may delay appropriate and prompt provision of information to consumers. Such a situation is unfortunate for all parties concerned, including the consumers of Kobayashi Pharmaceutical's products, business partners, and Kobayashi Pharmaceutical's officers and employees.

It is understood that Kobayashi Pharmaceutical will formulate and implement far-reaching measures to prevent recurrence of the Issue. However, unless consumer safety is instilled as the highest value and embodied in Kobayashi Pharmaceutical's day-to-day operations, it is unlikely that any preventive measures will be effective.

The Committee strongly expects that Kobayashi Pharmaceutical and its officers and employees will face up to the Issue and steadily implement true preventive measures.

End of Report

Translation Notes: Please note that the sections enclosed in quotation marks in this report indicate either quoted passages in Japanese or, as is visible from the context, defined terms. With respect to quoted passages in the English text, these translations were carried out by Kobayashi Pharmaceutical. Some have been translated to enhance their understandability in English and may not represent direct quotations from Japanese sources, where a direct translation would not sufficiently or appropriately convey the meaning.

Attachment 1.3 Primary Methods Used in the Investigation

1 Analysis and Careful Examination of Relevant Documents and Other Materials

The Committee analyzed and carefully examined the following relevant documents and other materials in the Investigation.

1.1 Basic materials

- Kobayashi Pharmaceutical's organization chart and personnel chart
- Kobayashi Pharmaceutical's internal regulations and other internal rules (including those that have been abolished) concerning quality control and product recall
- Kobayashi Pharmaceutical's regulations and other internal rules concerning requests for approval and authorization
- Interviewees' biographical ledger

1.2 Materials related to meeting bodies

- Meeting materials and minutes of the Board of Directors
- Meeting materials and minutes of the Audit and Supervisory
- Meeting materials of the GOM
- Minutes of, and materials used in, the meetings where the members of the Pharmacovigilance & Consumer Relations Division and other persons concerned participated and discussed the Issue
- Minutes of, and materials used in, the meetings where the reports to officers and other matter regarding the Issue was discussed
- Minutes of, and materials used in, the interviews with outside medical doctors and consultations with outside experts
- Other materials disclosed by the interviewees

1.3 Materials related to Three Beni-koji Related Products

- Manufacturing specifications for, and other materials concerning the manufacturing process of, the Three Beni-koji Related Products
- Materials concerning the ingredient analysis conducted on the Three Beni-koji

Related Products (analysis conducted in the process of manufacturing and shipping of the Three Beni-koji Related Products and in response to the Issue)
- Materials concerning the acquisition of the red yeast rice related business by Kobayashi Pharmaceutical, and materials concerning the business plan for the red yeast rice related business
- Other materials disclosed by the interviewees

1.4 Material related to the Issue

- "FastHelp" and other related materials concerning the Cases
- Materials prepared internally for responding to the Issue
- Other materials disclosed by the interviewees

2 Interviews

The Committee conducted a total of 63 interviews with 33 officers and employees of Kobayashi Pharmaceutical in the Investigation.

3 Outline of Digital Forensic Investigations

The Committee appointed FRONTEO Inc. ("**FRONTEO**") to preserve the electronic data recorded on personal computers, tablets, smartphones, and servers that a total of 30 officers and employees of Kobayashi Pharmaceutical use or used for business purposes, as well as some personal computers used for quality management in Kobayashi Pharmaceutical as follows. Then, as part of the Investigation, FRONTEO conducted a keyword search on some of the preserved electronic data, and conducted a primary review[1] on a total of 44,238 data including 18,090 emails and attached files, 1,166 chats, and 24,982 other files that were detected as a result of removing duplicate data, and the Committee conducted a secondary review on 2,461 data.

3.1 Preservation

The data subject to the investigation held by 30 persons that the Committee considered necessary to be examined were preserved by the following methods.

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[1] Including the sampling review by the Committee.

- Personal computers: 37 units of personal computers that Kobayashi Pharmaceutical lent to individuals or departments and the persons subject to the investigation used were preserved using FTK Imager manufactured by Exterro. In the event USB memory sticks or external HDDs were attached to the personal computers subject to the investigation, they were also preserved by using FTK Imager in the same manner as the personal computers.
- Some personal computers used for quality management: 16 devices were preserved using FTK Imager manufactured by Exterro. In the event external HDDs were attached to those personal computers, they were also preserved by using FTK Imager manufactured by Exterro in the same manner as the personal computers.
- Smartphones and tablets: 40 units of smartphones and tablets that Kobayashi Pharmaceutical lent to individuals were preserved by XRY manufactured by MSAB.
- Electronic data on the servers used by Kobayashi Pharmaceutical: Emails, files, and chats stored on the servers were preserved by using Vault manufactured by Google, and the file servers were preserved using Robocopy manufactured by Microsoft.

3.2 Restoring deleted files

With respect to the data preserved as described in 3.1 above, the deleted files in the personal computers, tablets, smartphones, and Google WorkSpace that the Committee determined to be examined were restored to the data in a state where they could be recognized as a file, and Gmails Google WorkSpace and the deleted files in Google Drive were restored by using Vault manufactured by Google.

3.3 Processing

Except for the data held by certain persons that the Committee considered unnecessary to be examined, and part of the data that could not be opened due to corruption or protection by passwords, etc., the data preserved and restored as described in 3.1 and 3.2 above were pre-processed (processed) to eliminate system-related data and duplicate data.

3.4 Keyword search

The data processed as described in 3.3 above were narrowed down by utilizing keywords defined by the Committee, and 48,981 documents were extracted and 44,238 documents excluding duplicate email data were subject to review.

3.5 Review

FRONTEO conducted a primary review on the documents subject to examination as described in 3.4 above in accordance with the review protocol agreed upon with the Committee. With the primary review, FRONTEO used an AI[2] document scoring function to efficiently conduct the review. The Committee conducted a secondary review based on the result of the primary review conducted by FRONTEO.

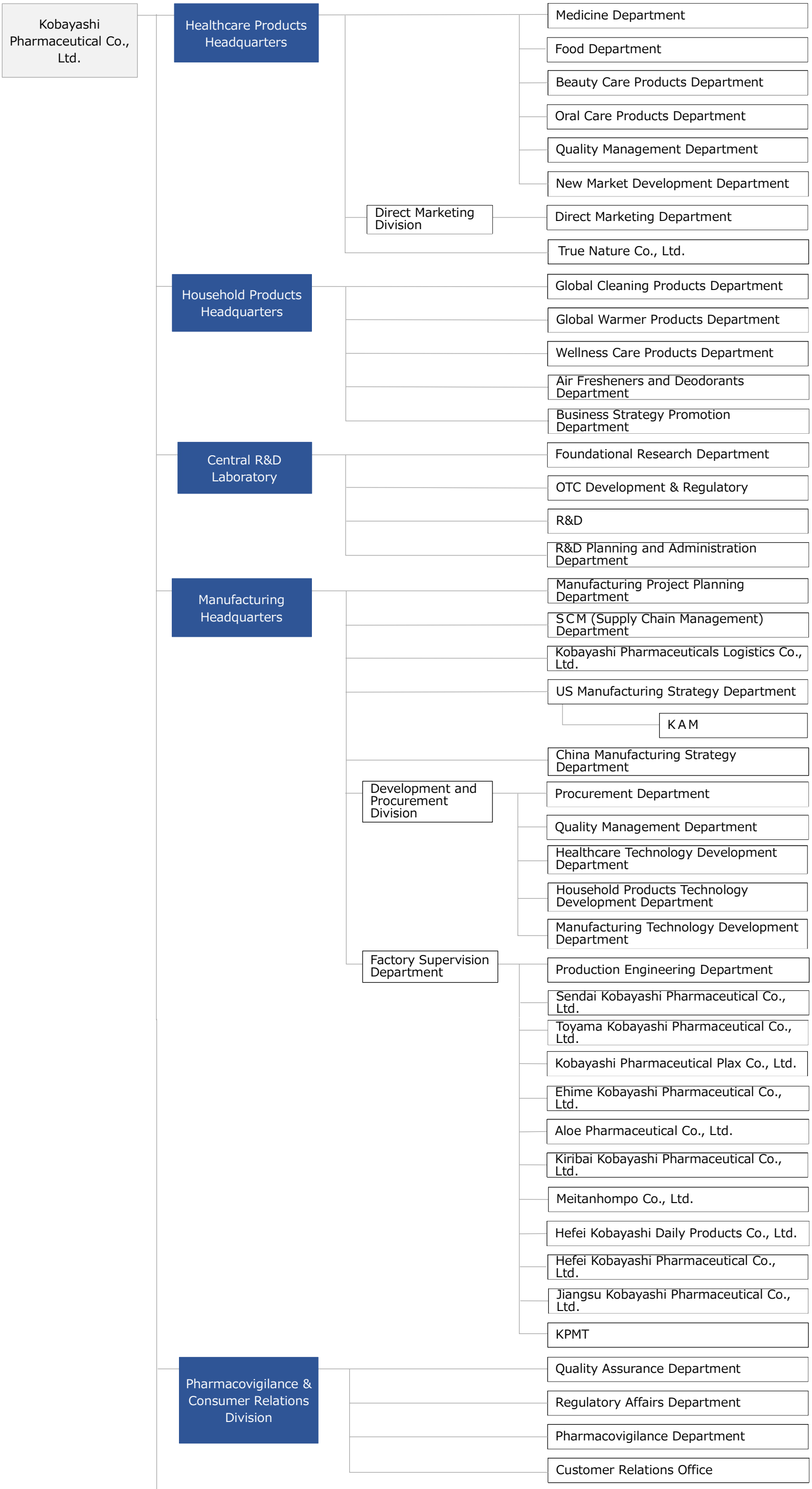
4 On-site Inspection

On June 7, 2024, the Committee visited the Kinokawa Plant to receive explanations on the manufacturing process, quality management system, etc. of the Products from officers and employees of Kobayashi Pharmaceutical and Meitanhompo, and inspected the manufacturing site of the Products. In addition, on June 8, 2024, the Committee visited the Osaka Plant and inspected the current status of the Osaka Plant, and visited the head office of Kobayashi Pharmaceutical to exchange opinions on the general quality management system of Kobayashi Pharmaceutical with persons belonging to Pharmacovigilance & Consumer Relations Division, etc.

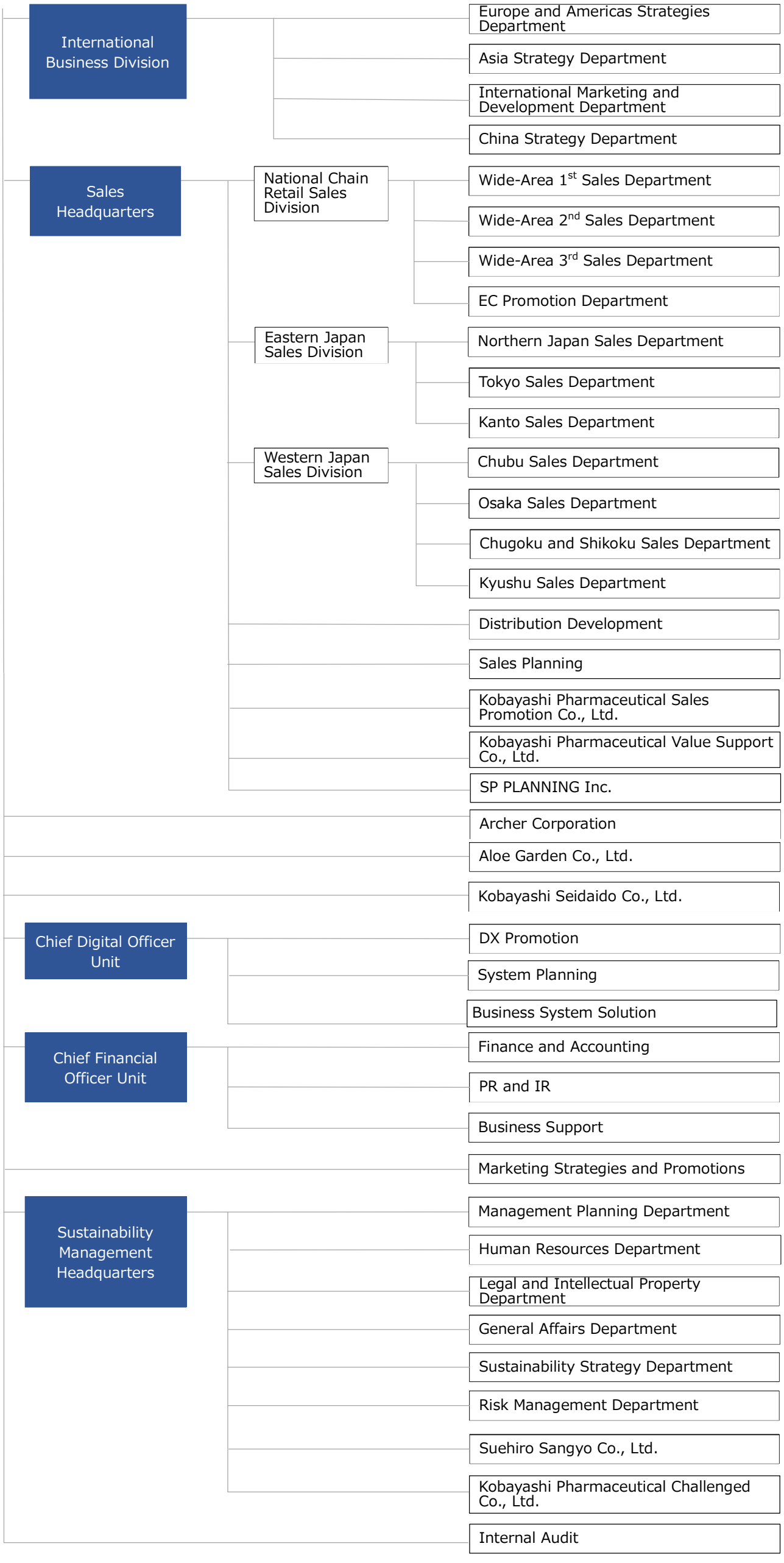
End.

[2] "KIBIT" developed by FRONTEO was used.

Attachment 2.2 Organizational Chart



Attachment 2.2 Organizational Chart



Attachment 3.1　List of hospitalizations and outpatient cases

Case[1]	Hospitalization/Outpatient, Etc.[2]	Date on which Information was First Received	Person who Provided the Information	Summary of Contact Regarding the Case
Case 1	Hospitalization	January 15, 2024	A medical doctor	・The patient, who had ingested the Product, had acute kidney failure (later diagnosed as tubulointerstitial nephritis), was hospitalized for about three months, and was discharged after undergoing dialysis and steroid treatment, etc.
Case 2	Hospitalization	January 31, 2024	A consumer	・A medical doctor pointed out abnormalities in the patient's kidney tubes, and indicated that the cause might be health food products, traditional Chinese medicines, or pharmaceutical products that the patient had ingested, including the Product. ・The patient was hospitalized for about one week, and underwent outpatient treatment after discharge.
Case 3	Hospitalization	February 1, 2024	A medical doctor	・In these three hospitalization cases of tubulointerstitial nephritis, all of the patients had ingested the Product. ・The patient in Case 3 was discharged on February 17, and underwent outpatient treatment thereafter.
Case 4	Hospitalization			
Case 5	Hospitalization			
Case 6	Outpatient, etc.	February 1, 2024	A consumer	・The patient had abnormal levels regarding kidney function, to which a medical doctor indicated the possibility of tubulointerstitial nephritis, although this was not certain.

[1] Kobayashi Pharmaceutical reported a total of 14 cases concerning patients in their 40s to 70s (12 females and 2 males) at the GOM held between Tuesday, February 13 and Tuesday, March 19.

[2] Even in cases of hospitalization, if the patient was only hospitalized for examination, they are classified as "outpatient, etc."

Attachment 3.1 List of hospitalizations and outpatient cases

				The patient was scheduled to be hospitalized for about two months, but the patient was not actually hospitalized.
Case 7	Outpatient, etc.	June 7, 2022	A consumer	・ The patient developed symptoms described in the package insert of the Product, such as muscle pain, fatigue, and dark urine, and underwent outpatient treatment. ・ The patient's symptoms lessened after discontinuing ingestion of the Product.
Case 8	Outpatient, etc.	January 11, 2024	A consumer	・ The patient had abnormal levels regarding kidney function and underwent outpatient treatment.
Case 9[3]	Outpatient, etc.	February 16, 2024	A consumer	・ The patient was hospitalized for examination following the onset of acute kidney failure, and underwent outpatient treatment thereafter. ・ The spouse of the patient who provided the case information to Kobayashi Pharmaceutical also suffered from kidney damage after ingesting the Product, and has been undergoing outpatient treatment.
Case 10	Hospitalization	February 27, 2024	A medical doctor[4]	・ The patient, who had ingested the Product, developed serious kidney damage (later diagnosed as tubulointerstitial nephritis[5]) and was hospitalized for about one week.
Case 11	Outpatient, etc.	March 4, 2024	A consumer	・ The patient's medical checkup indicated abnormal levels regarding kidney function, and the patient was planning to be hospitalized for examination.
Case 12	Outpatient, etc.	March 7, 2024	A consumer	・ The patient had abnormal levels regarding kidney function, of which the cause was unknown, and was planning to undergo a re-examination around April.

[3] As stated in the "Summary of Contact Regarding the Case," it was informed that both husband and wife who had ingested the Product had suffered kidney problems, but in accordance with the GOM's classifications only the wife's case is counted as a case.
[4] Kobayashi Pharmaceutical was also contacted by the patient on February 27.
[5] The exact record showed the names "acute tubular disorder and interstitial nephritis."

Attachment 3.1 List of hospitalizations and outpatient cases

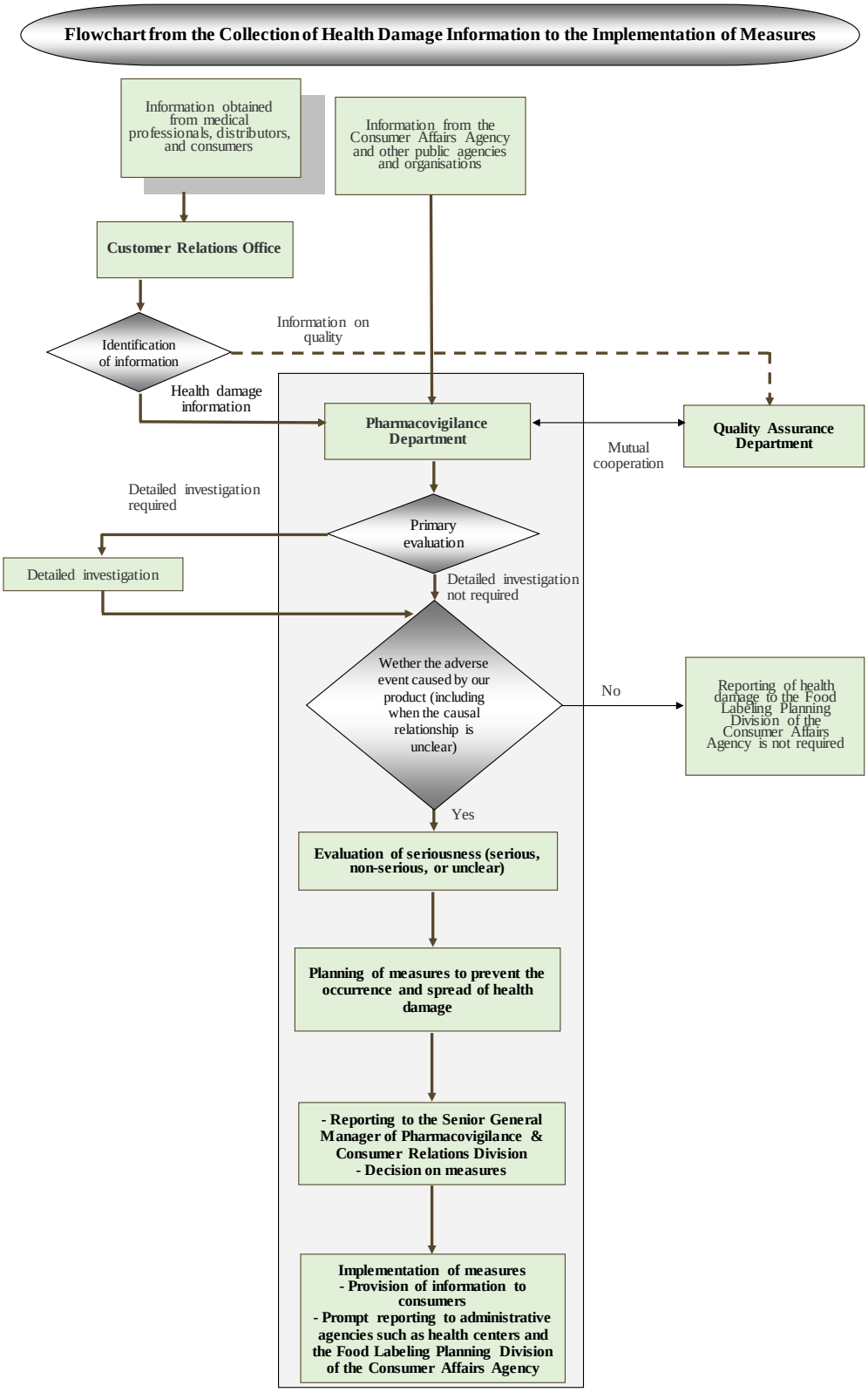
Case 13	Outpatient, etc.	March 7, 2024	A consumer	・ The patient's kidney function levels worsened after ingesting the Product, and the patient underwent an examination by a nephrologist.
Case 14	Outpatient, etc.	March 15, 2024	A Consumer Affairs Center	・ In November 2023, the patient was found to have proteinuria, etc., and in December, the patient was hospitalized for examination. ・ As a result of the examination, in February 2024, the patient received a diagnosis from the medical doctor of tubulointerstitial nephritis and drug-induced kidney problems, and underwent outpatient treatment.

* "Case 1," "Case 2," "Case 3," through "Case 14" are used to refer to each Case in the body of the report.

* This Table is based on the information that Kobayashi Pharmaceutical had ascertained as of the Mar. 19 GOM, and does not reflect all of the information available at the time the information was initially provided. The information in the "Summary of Contact Regarding the Case" is also as of the Mar. 19 GOM, and the condition of each patient may have changed since then.

Attachment 4.3.2.1 Workflow in Cases of Health Damage

1. Reporting Flowchart



2. Flow for Determining Food Collection (Chart 2) in the Flow for Determining Product Collection