[Translation]

September 17, 2024

To Whom It May Concern:

Notice Regarding the Formulation of the Reoccurrence Prevention Measures, Etc.

As stated in "Summary Conclusion Issued by the Board of Directors Based on the Fact-Finding Committee's Investigation Report" dated July 23, 2024, Kobayashi Pharmaceutical, Co., Ltd. (Head office: Osaka, Japan; President: Satoshi Yamane) ("Kobayashi Pharmaceutical") received from the Fact-Finding Committee an investigation report regarding the series of responses taken by Kobayashi Pharmaceutical regarding the issue that certain Red Yeast Rice ingredients of Red Yeast Rice related products sold by Kobayashi Pharmaceutical may have contained unanticipated components (this "Matter"; such report, the "Investigation Report").

We hereby announce that we have passed resolutions on the reoccurrence prevention measures dated today, taking into account the matters pointed out in the Investigation Report, as follows.

From now on, the entire company will work together to reexamine the issues regarding our internal control system and quality control system, which have also been pointed out in the Investigation Report, and change the mindsets of all officers and employees concerning the quality and safety of our products. In addition, we will work earnestly to restore the trust in Kobayashi Pharmaceutical so that customers can use our products with peace of mind, by promptly and thoroughly implementing the reoccurrence prevention measures announced today.

Details

Outline of the Reoccurrence Prevention Measures

Based on the opinions offered by the Fact Finding Committee through its Investigation Report, we established specific Reoccurrence Prevention Measures comprised of the three pillars of policies, namely (1) Changing Mindsets and Enhancing Systems concerning Quality and Safety, (2) Fundamental Changes to Corporate Governance, and (3) Rebuilding a New Kobayashi Pharmaceutical through Unity. From now on, we will continue to implement these Reoccurrence Prevention Measures. Please refer to the specific details of these established Reoccurrence Prevention Measures as described in the Attachment "Reoccurrence Prevention Measures." An overview of these Measures is provided below.

(1) Changing Mindsets and Enhancing Systems concerning Quality and Safety

We will work to thoroughly implement "quality and safety first" and change the mindsets concerning quality and safety of our officers and employees.

In addition, we will enhance the quality assurance and management systems. To enhance the quality assurance system, responsible departments will be clarified, quality control systems will be improved, and a new specialized department will be established. To enhance the management system, governance systems in plants will be improved,

relevant rules will be developed, workflows will be reviewed, and personnel evaluation systems will be reformed .

(2) Fundamental Changes to Corporate Governance

We will implement fundamental reforms to the corporate governance from a number of perspectives. Specifically, we will continue to make progress on the respective issues of breaking free of dependence on the founding family in managing the Company, re-examining organizational structures, strengthening supervision by a Board of Directors that is centered around Outside Directors, abolishing the GOM (the Group Operating Meeting), establishing a crisis management system, enhancing risk and compliance systems, improving external communication and information distribution, and making choices based on resources.

(3) Rebuilding a New Kobayashi Pharmaceutical through Unity

We will rebuild our company through unity with all officers and employees and by implementing measures to eliminate homogeneity inherent in Kobayashi Pharmaceutical and strengthen diversity. Through these efforts, we will work to reform the corporate culture that is essential to build a “new Kobayashi Pharmaceutical.”

From now on, we will steadily and faithfully implement the reoccurrence prevention measures. We also deeply reflect on the fact that we have caused considerable concern and inconvenience to our customers, business partners, shareholders, and investors due to this Matter, and would like to fulfill our responsibilities by making certain contributions to society in addition to the implementation of the reoccurrence prevention measures.

By having all officers and employees always keep in mind that the activities set forth in the reoccurrence prevention measures should not end as temporary activities, and now and then revisit how they felt on this very day, we, as the entire company, will pursue the building of a new Kobayashi Pharmaceutical, based on a change in the mindsets of all officers and employees concerning quality and safety.

End

1. Outline of the Reoccurrence Prevention Measures

Following the announcement of the Matter on March 22, 2024, an investigation into the cause of the Matter has been progressing under the leadership of the Ministry of Health, Labour and Welfare (MHLW), Osaka City, and the National Institute of Health Sciences (NIHS), and Kobayashi Pharmaceutical has been cooperating in the activities relating to said cause investigation. With respect to the progress of the activities relating to this cause investigation, on May 28, 2024, the MHLW suggested the possibility that health damage had been caused by multiple compounds containing puberulic acid produced by the growth of a certain blue mold, which had been mixed into red yeast rice (Beni-Koji) during cultivation.

While activities relating to the cause investigation into the Matter are currently ongoing, we has formulated these Reoccurrence Prevention Measures in order to resolve, among others, manufacturing and quality issues, the issues indicated in the Investigation Report of the Fact Finding Committee, and the issues related to the state of information disclosure practices to government authorities and society at large as announced in the press release dated August 1, 2024, etc.

The following three policies constitute the main pillars of these Reoccurrence Prevention Measures.

(1) Changing Mindsets and Enhancing Systems concerning Quality and Safety
(2) Fundamental Changes to Corporate Governance
(3) Rebuilding a New Kobayashi Pharmaceutical through Unity

The policies under (1) are comprised of changing mindsets with a core “quality and safety first,” as well as enhancing the quality assurance and management systems. To enhance the quality assurance system, responsible departments will be clarified, quality control systems will be improved, and a new specialized department will be established. To enhance the management system, governance systems in plants will be improved, relevant rules will be developed, workflows will be reviewed, and personnel evaluation systems will be reformed.

Devised over a period of self-examination, the policies under (2) consist of fundamental reforms to the previous corporate governance, which led to the occurrence of the Matter. We will continue to make progress on the respective issues of breaking free of dependence on the founding family in managing the Company, re-examining organizational structures, strengthening supervision by a Board of Directors that is centered around Outside Directors, abolishing the GOM (the Group Operating Meeting), establishing a crisis management system, enhancing risk and compliance systems, improving external communication and information distribution, and making choices based on resources.

The policies under (3) are essential reforms made to the corporate culture in order to build a “new Kobayashi Pharmaceutical” from the combined efforts of the entire management team and all employees.

The specific details of the Reoccurrence Prevention Measures are as stated below.

2. Changing Mindsets and Enhancing Systems concerning Quality and Safety

(1) Changing Mindsets: “Quality and Safety First”

It was indicated in the Investigation Report that Kobayashi Pharmaceutical lacked awareness regarding the safety of health food products.

Therefore, in addition to first conducting education and training on quality and safety for all officers and employees in a well-planned manner, we will provide a discussion forum whereby each officer and employee will come to view quality and safety as “my own responsibility.” Through such initiatives, all officers and employees will reconfirm the importance of “providing peace of mind to our customers.”

In addition, a corporate culture that believes in prioritizing quality and safety requires the

continuation of steady efforts, which the company president must lead. The president will become the standard bearer and regularly deliver messages concerning quality and safety. The management team will increase opportunities for dialogue with the employees involved in maintaining and managing quality and foster a "quality and safety first" mindset.

Further, we will also firmly integrate the "quality and safety first" mindset into our business plans. Specifically, we will review the goals stated in our Medium-Term Management Plan and position polices concerning quality and safety, including these Reoccurrence Prevention Measures, as key components. In this review of the Medium-Term Management Plan, we will establish the "quality and safety first" mindset as the company's most important issue. We will also remove "consecutive profit increases" from the goals stated in our Medium-Term Management Plan, which until now had been touted as an important management goal. We will create an environment in which we can carry out the investments required for improving quality and safety. In addition, we will also adopt perspectives of selecting and concentrating on our core businesses.

Finally, the president will display strong leadership under the "quality and safety first" mindset, even in emergencies, and will make prompt decisions which prioritize quality and safety.

(2) System Enhancement 1: The Quality Assurance System

(A) Clarifying Responsible Departments

At Kobayashi Pharmaceutical, the Pharmacovigilance & Consumer Relations Division oversees the quality assurance system and the safety control system and is an organization that serves as a check-and-balance function on the business divisions. However, as stated in the Investigation Report, the Pharmacovigilance & Consumer Relations Division could not perform this role with respect to the Matter.

Accordingly, going forward, we will also realize a "quality and safety first" mindset from a system perspective. Therefore, we will clearly position the Pharmacovigilance & Consumer Relations Division as the department responsible for the quality assurance and safety control systems, independent from the business divisions. Further, we will make clear that the Pharmacovigilance & Consumer Relations Division is to assume the roles and responsibilities of auditing the quality and safety control processes of the business divisions, the Manufacturing Headquarters, and the plants.

In addition, the Pharmacovigilance & Consumer Relations Division will prescribe standards based on feedback from the business divisions, the Manufacturing Headquarters, and the plants in order to further improve the quality and safety of our products and will update those standards from time to time.

(B) Improving Quality Control Systems

We have set up quality control sections in departments and divisions in the "First Line" (i.e., development departments, the Manufacturing Headquarters, and plants), and thereby responded to quality control issues that arose therefrom. Nevertheless, a decline in staff expertise was seen in those quality control sections due to frequent personnel rotations in a short period of time. In business divisions, for instance, the quality control promotion departments and divisions in the development departments also started supporting product development, and that made it unclear with respect to the role of the quality control promotion departments and divisions functioning as quality control sections. In addition, the "Second Line"(i.e., the Pharmacovigilance & Consumer Relations Division) shifted the focus of its quality audit operations only to adequacy audits of the systems for quality control operated by the First Line, and this made it harder for the Second Line to fully perform the desirable functions in controlling quality.

Among the manufacturing departments and divisions in the First Line, the Quality Management Department has performed the quality control and audit operations for OEMs. In the meantime, in Kobayashi Pharmaceutical Group plants, there were differences in the degree of fulfillment of quality control improvement activities among the plants, depending on the plant manager (i.e., the president of a subsidiary if the plant is operated by a subsidiary of Kobayashi Pharmaceutical; hereinafter the

same meaning applies) and people in the management level of the plant, and the Quality Management Department could not perform the audit operations for the plants as it has performed for OEMs. Also, in the Pharmacovigilance & Consumer Relations Division in the Second Line, for the quality audit at the plants, save the pharmaceutical regulatory affairs for the manufacturing of pharmaceutical, etc., clear division of responsibilities has not been established, thus the notion where the responsibility lies in terms of quality audits and checks-and-balances for our plants was unclear within the entire company of Kobayashi Pharmaceutical. Furthermore, the management team as well as the management departments and divisions of our Headquarters could not fully understand such a situation, and thus could not correctly control the scope of responsibility and division of roles between each organizational unit.

As explained above, because of the decline in expertise in the *monozukuri* (manufacturing) function of the First Line and the inherent vagueness in the systems for quality control and audit of the Second Line, the relevant departments and divisions could not achieve sufficient improvement required to meet the demand for increased production in keeping with sales growth.

From now on, as stated in (A) above, we will have the Pharmacovigilance & Consumer Relations Division, which is categorized as the Second Line, clearly positioned as a body guaranteed with independence from the business, and clearly define the Pharmacovigilance & Consumer Relations Division to have the role and responsibility for process auditing of the quality and safety control of the First Line (i.e., development departments, the Manufacturing Headquarters, and plants). In addition, the Pharmacovigilance & Consumer Relations Division will be responsible for establishing standards to make our products higher quality and safer based on feedback from the First Line and for maintaining the standards up to date at all times.

At the same time, we will reassess the way the personnel rotations will be implemented, which used to be conducted in a short period of time for the purpose of nurturing generalists up to now, and will implement a structure that could (i) increase the expertise in the First Line (i.e., development departments, the Manufacturing Headquarters, and plants), the departments and divisions that would mainly secure the quality control of our products and (ii) clearly define the quality control departments and divisions to assume only the role of quality control, as originally expected of them.

In addition, we will strength the interactive collaboration between quality control and audit departments and divisions in the First and Second Lines, and will establish a system in which the Second Line will indicate a company-wide, unified standard regarding adherence to the manufacturing processes and development of a safety and health management system, and a system in which the quality control departments and divisions in the First Line will respond through each field having responsibility to fulfill such standard.

(C) Creating a New Specialized Department

As stated in the Investigation Report, rather than reporting to governmental authorities or conducting a product collection in this Matter, we focused on determining the cause based on the interpretation of the Pharmacovigilance & Consumer Relations Division 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." However, there is no clear statement in administrative documents to support this interpretation by the Pharmacovigilance & Consumer Relations Division, which was not appropriate.

In general, when interpreting laws, regulations, and guidelines etc., regarding important issues such as this Matter, it is first necessary to take measures such as consulting with external experts and authorities at an early stage. In addition, rather than adopting the usual division of duties, it would have been appropriate for the Legal and Intellectual Property Department and other administrative departments to have been involved.

However, we rarely conducted such consultations and involvement as a basic rule, and our checks-and-balances on the Pharmacovigilance & Consumer Relations Division did not function. As a result, the interpretation of the Pharmacovigilance & Consumer Relations Division was adopted on an as-is basis.

Accordingly, we will create a new department that has the appropriate authority and independence

to handle laws and regulations related to product development and manufacturing in a professional manner and to provide appropriate interpretations. This department will check the work documents established by the Pharmacovigilance & Consumer Relations Division from the perspective of whether they are based on related laws, regulations, and guidelines, and will consult with external experts as necessary.

(3) Enhancing Systems (2): Management Systems

The manufacturing of our Red Yeast Rice related products requires a long period of cultivation of about 50 days. This Matter is said to have possibly been caused directly due to this cultivation process. This process is unique to the product, and we basically do not manufacture other products using a similar manufacturing process to this process. That said however, there were a few things that should be thoroughly examined as a matter of quality and safety systems at Kobayashi Pharmaceutical when we sincerely reflected upon this Matter. Accordingly, in order for us not to allow an incident similar to this Matter from reoccurring in the future, and in addition to reviewing the quality control systems currently implemented in all plants, we will work to strengthen our management system for quality and safety as set out below.

(A) Improving Plant Governance Systems

As also pointed out in the Investigation Report, our "quality management system was left to the field." In fact, at the Osaka Plant and the Kinokawa Plant, the task of identifying issues related to everyday operations at the plant was pretty much left to the plant managers and the people in the management level.

We used to set up quality control departments and divisions in each plant, assigned a person in charge for each such department and/or division, and conducted day-to-day production and improvement activities under the direction and chain of command of the plant managers. In addition, as collaboration efforts between the Manufacturing Headquarters and the plants concerning quality control, activities such as providing a quality-related report through a quarterly plant operation review or the Monthly Report, monthly cross-out sharing of quality defects and/or important challenges amongst all plants led by the Quality Management Department of the Manufacturing Headquarters, and a plan-do-check-action (PDCA) cycle of key areas for improvement based on these reports and information sharing were implemented. However, for day-to-day production activities, except for the manufacturing lines of pharmaceutical products, etc., we did not conduct auditing from a third-party viewpoint including process auditing of manufacturing fields, which should have periodically been conducted by headquarters or similar departments/divisions. As a result, our system was that of a system that may cause variation in improving quality and safety challenges at each plant, depending on the plant managers and the people in the management level of that plant.

Hence, from now on, we will perform a regular auditing of each plant by the Quality Management Department of the Manufacturing Headquarters, dedicated on quality control. In addition, we will establish a system that will ensure that outside third-party checking is conducted.

In addition, while we has 8 plants in Japan and 4 plants overseas, the Factory Supervision Department that performed the role of supervising all of those plants was run by only one single general manager, who was at the top of the reporting line, and no one else that was necessary to perform the supervising function of the plants was assigned below that general manager. Thus, the Factory Supervision Department did not have a sufficient system that could provide detailed guidance tailored to actual situations of each plant and realize the PDCA cycle.

To address this issue, and in order to have this plant supervision function appropriately performed, we will newly establish the "Factory *Monozukuri* (Manufacturing) Promotion Department (tentative name)" and assign the necessary number of staff to perform the function. We will thereby enhance the function of identifying the challenges faced by each individual line in each plant and/or in management of the plant as a whole and the examination function of those challenges. In addition, in order to make issues of each plant more likely to come to light, we will reinforce communication between managers and workers on site at each plant, as well as between the Manufacturing Headquarters and each plant.

Further, in terms of safety and health management, while we have operated our business in compliance with the relevant standards when such a standard is prescribed by laws and regulations, etc., in cases where no such standards were prescribed by laws and regulations, etc., we have allowed each plant, on its own responsibility, to set a standard and operate its work by using the results of discussions between the development departments and each plant or by referencing the industrial standards of manufacturing vendors, etc., in the same business category as the relevant product. Therefore, there were aspects regarding such standards and operations that the Manufacturing Headquarters could not supervise or oversee as a whole.

Accordingly, from now on, we will establish comprehensive safety and health management standards for each individual product category, enhance training for the safety and health management aspects, and aim to further improve the maintenance and management of the safety and health environment of plants and their facilities.

(B) Developing Relevant Rules

As was stated in the Investigation Report, Kobayashi Pharmaceutical had several internal rules for actions to take upon occurrence of health damage that were mutually contradictory to each other, and the interpretation of those internal rules were also not systemically organized.

Therefore, we will consolidate internal rules by centralizing all laws, regulations, guidelines, and other rules applicable to each product category and establish a clear-cut system of internal rules.

In addition, we believe that it is necessary to foster a shared awareness concerning quality and safety among all directors, officers, and employees in order to correctly understand and apply the internal rules for quality and safety. In this regard, although we already had established a "quality assurance policy" that sets forth our policy concerning quality and safety, the measures to promote dissemination of this policy were insufficient.

Thus, from now on, we will be conscious of this "quality assurance policy" on a daily basis by implementing measures such as having all directors, officers, and employees recite the "quality assurance policy" at our morning meetings and making sure the same is thoroughly understood and disseminated throughout the organization.

Further, in order to ensure that all departments and divisions involved in manufacturing, R&D, and quality control/assurance are on the same page and can promote the activities enhancing the quality, we will establish a new "*monozukuri* (manufacturing) quality-oriented action policy" that plainly illustrates the contents of the "quality assurance policy" in specific rules of conduct.

(C) Reviewing Workflows

(a) Collaboration Between Development Departments and Plants

At Kobayashi Pharmaceutical, it had become more difficult for the processes of sharing and reflecting upon issues that arose among development departments and plants to function as effectively as they had in the past. Namely, for manufacturing processes that had been transferred to plants from development departments, even if there were issues noticed by the development departments, those issues were less likely to be shared with the relevant plants. At the same time, among some issues that arose at a plant, there were issues that were caused by some standards, etc., vaguely set by a development department, and there were cases where such issues were not communicated to the development department. As a result, there were issues in the manufacturing process that have not been fundamentally solved.

To this end, from now on, we will regularly hold a "mass production review meeting (tentative name)," which will provide opportunities to development departments and plants to discuss issues and challenges in the manufacturing process, share issues and knowledge of development departments and plants with each other, and review and improve from time to time the ongoing manufacturing processes. We will ensure that the general manager of the Manufacturing Headquarters and general managers of development departments mandatorily attend this meeting, and, through this meeting, we will establish a system that allows both sides to collaborate,

centralize knowledge and technology of the organization as a whole, and create an organizational culture of “quality and safety first” in which all departments sincerely tackle the issues and challenges faced by the manufacturing field of plants.

Simultaneously, for existing products, we will establish a cross-departmental quality enhancement team comprised of members from development departments and the Manufacturing Headquarters. Through these efforts, we will promote improvement activities that go back to the phase of identifying issues at plants and the design phase.

(b) Improvement of Manufacturing Management and Maintenance Control, Etc., in New Technology Area

The Red Yeast Rice related business was a business that Kobayashi Pharmaceutical assumed from another company. Because of that, at the manufacturing lines of the Red Yeast Rice related products, Kobayashi Pharmaceutical did not originally have sufficient cultivation-related technologies. As a result, the system was one in which Kobayashi Pharmaceutical’s manufacturing management had to rely on the personnel on-site transferred from the company from which Kobayashi Pharmaceutical assumed the business.

In addition, as a result of not being able to assign sufficient resources to the manufacturing lines of the Red Yeast Rice related products, training of new engineers did not work, and this allowed the situation of relying on the personnel on-site to continue.

Reflecting on that situation, from now on, we will reconsider the way we calculate the purchasing managers index (PMI) upon entering into or expanding our business in any technological area that is new to us so that we would be able to continuously check the quality and implement quality improvement measures. In addition, we especially will strengthen the manufacturing management structure of a product after production begins and enhance the maintenance control of quality through making sufficient investments, nurturing and training human resources, while incorporating opinions of outside experts as necessary.

(c) Strengthening Product Inspections

In the manufacturing lines for the Red Yeast Rice related products, we went through a process of confirming the content amount of monacolin K, the valuable ingredient of the products, at the time of shipment. However, the procedure was not designed for confirming whether any unintended ingredients are contained in the Red Yeast Rice ingredients, and as a result, we were unable, as was in this Matter, to realize that there were unintended ingredients in the products.

For this reason, we will implement measures such as conducting multiple testing, etc., depending on the characteristics of a product and adopting procedures to confirm whether ingredients other than the standard ingredients are contained in a manufactured product, and thereby enhance the product inspection process.

(D) Reforming Personnel Evaluation Systems

Our personnel evaluation system thus far had focused on the results of day-to-day work such as sales, profits, cost reductions, or other business performance, as well as the number of items being developed, volume of inventory left, or whether or not an out-of-stock situation existed. In addition, the company-wide evaluation system required to set, as an evaluation item, target values for results such as the number of accidents or disposal costs incurred with regard to the quality-related indicators of manufacturing departments and did not require setting evaluation indicators for improvement therefrom or implementation of prevention processes thereof. Thus, any approaches to quality improvement and submissions of improvement proposals were considered subordinate to business operations such as product supply activities and cost reduction efforts.

From now on, in order to properly evaluate the performance of steady day-to-day work operations concerning quality and safety, we will introduce a performance evaluation system that includes, as evaluation items, any activities that contribute to quality and safety.

Specifically, we will highly evaluate activities that would prevent problems with quality and safety from occurring. Including this point, we will revise the performance evaluation system to ensure more weight is placed on appreciation of steady efforts contributing towards quality and safety, which are less likely to manifest in short-term business results.

3. Fundamental Change to Corporate Governance

(1) Breaking Free of Dependence on the Founding Family in Managing the Company

Since Kobayashi Pharmaceutical was founded, the founding family has consistently held the position of president. However, as described in the press released dated July 23, 2024 and titled "Notice Regarding Change of Representative Directors and Voluntary Return of Part of Officers' Compensation," a person who is not a member of the founding family has been appointed as the new president for the first time so that we reflect on this Matter and show both internally and externally that we are determined to make a fresh start with a new system.

We will break free of our dependence on the founding family. First of all, the new president will take the lead and steer the management of Kobayashi Pharmaceutical in the direction of "quality and safety first."

(2) Re-examining Organizational Structures

We will review this Matter and re-examine whether the organizational structures that form the basis of corporate governance will continue to be appropriate in the future. Specifically, while Kobayashi Pharmaceutical is a company with board of company auditors, if it is determined that it would be more appropriate from the perspective of strengthening corporate governance to transition to a company with audit and supervisory committee, etc., we will proceed with examination on such transition.

In order to acquire a more effective supervisory function with enhancing corporate value, while continuing with the structure of the Board of Directors, in which the majority of the members are outside directors, we will continue to explore the optimal structure and skills matrix. Specifically, we will consider inviting people with broad experience and technical expertise in the sectors of quality, pharmaceuticals and food, as well as people who can further strengthen internal controls, to appoint them as Directors.

(3) Strengthening Supervision by Board of Directors

(A) Strengthening Supervision by Outside Directors

In order to ensure the effectiveness of the Board of Directors, the role of the chairman of the Board of Directors, which has until now been performed by the Chairman, will be taken by an Outside Director. The necessary amendment to the Articles of Incorporation will be made to make this arrangement permanent.

In addition, the Board of Directors will supervise the implementation of the Reoccurrence Prevention Measures under the chairman of the Board of Directors who is an Outside Director. It will also set an agenda that contributes to strengthening corporate governance.

Also, the Outside Directors will strengthen the supervision of the effectiveness of the internal control system and risk management system. One of the methods for doing this is to improve the sharing of risk information, etc. by strengthening the system for collaboration between the Outside Directors and the Audit and Supervisory Board Members.

(B) Regular Meetings between the Board of Directors and the Executive Side

This Matter was a serious risk factor. However, for about two months from the first case report to the sharing of information with the Outside Directors, the discussion on the responses to be taken was conducted internally without the Outside Directors being aware of the risk factor.

Based on this reflection, we will ensure that information is provided to the Board of Directors in a timely and appropriate manner. Specifically, information will be extensively shared with the Board of Directors even at the stage when there is uncertainty about whether or not a report is necessary. In addition, in order to ensure close communication between the Board of Directors and the executive side, we will hold regular meetings between the Board of Directors and the executive side.

Furthermore, we will establish information sharing rules to ensure that information is shared promptly with the Board of Directors and the Audit and Supervisory Board in the event of emergencies. Until now, the Risk Management Department has reported to the Board of Directors on the risks that it has identified from the monthly reports and identified as being of high urgency and importance in consultation with the general managers in the corporate departments, after going through the discussion by the management committee. However, from now on, the management committee, instead of the Risk Management Department, will take responsibility for selecting important risks regardless of their urgency or importance, and will share information with the Board of Directors every month.

Alongside the creation of such a system, we will also always ensure that "bad news will be reported first and promptly (bad news first)" on a company-wide basis.

(C) Timely Sharing Information with Audit and Supervisory Board Members

The permanent members of the GOM include the Full-time Audit and Supervisory Board Members, and the Full-time Audit and Supervisory Board Members were also involved in discussions about this Matter. However, it ended up that no early announcement or collection took place.

Therefore, to ensure that effective audits are carried out by the Audit and Supervisory Board Members, we will strengthen communication, including the sharing of information from the executive side to the Audit and Supervisory Board Members and the Audit and Supervisory Board.

(4) Abolishing the GOM

In the Investigation Report, it has also been pointed out that the GOM was practically dysfunctional in responding to this Matter. This is due to the Executive Officers who were attendees of the GOM identifying this Matter as a problem that can be handled at the GOM held once a week, and it is undeniable that the risk awareness was low.

One of the factors why the GOM did not function effectively is, due to the large number of attendees, the GOM was becoming a "place for listening" to the reports of the person in charge at the responsible department rather than a "place for discussion" amongst the members. In fact, the response plan for this Matter reported by the person in charge of the Pharmacovigilance & Consumer Relations Division or other divisions was not substantially changed by the discussions at the GOM.

Therefore, we will abolish the GOM.

We will newly establish the "Management Executive Meeting" composed of the President and a small number of Executive Officers as the final decision-making body of the executives of the Kobayashi Pharmaceutical Group, which has influence over the management. In addition, as a place for having information shared from each department and discussing issues from diverse perspectives, the "Group Council" composed of the Executive Officers, some heads of divisions, deputy senior general managers, and general managers in the corporate departments will be established.

By streamlining the decision-making body through such policies, we will enhance our sensitivity to risks and improve the quality and speed of our decision-making.

(5) Establishing a Crisis Management System

(A) Response System where the President is the Person in Charge

As stated in (4) above, the responses to this Matter were mainly considered at the GOM, and no prompt and effective top-down response was taken by establishing a countermeasures meeting body .

One reason for such response is, since the current Crisis Management Regulations, which stipulate

the establishment of a Crisis Management Headquarters, are regulations mainly concerning crisis management such as earthquake response measures, they were not suitable for determining matters such as collection of the products and public announcements.

Therefore, necessary regulations will be developed in order to make it possible to convene an emergency meeting concerning quality and safety with the President being the person in charge, in a case of an emergency, such as this Matter, where serious health damage occurs to a person who has ingested our products.

(B) Risk Management System Assuming Emergencies

At Kobayashi Pharmaceutical, the establishment of a response system depending on the degree of importance of the quality risk was insufficient.

Therefore, by identifying company-wide risks and reviewing the status of the responses depending on the degree of importance under the leadership of the Risk Management Department, we will review the risk management system assuming a specific emergency response scenario.

(C) Internal Information Sharing System in case of an Emergency

In the case of this Matter, it was necessary to promptly and appropriately share internal information while paying attention to the protection of personal information and management of insider information. However, for example, as pointed out in the Investigation Report, the usage of the internal information system was insufficient.

Therefore, we will consider establishing a system that allows for information sharing which prioritizes quality and safety under the leadership of the emergency meeting concerning quality and safety prescribed above, that is different from ordinary operations, in case of an emergency.

(6) Enhancing Risk and Compliance Systems

(A) Reorganizing the Governance Promotion Meeting

In order to strengthen our preparedness for quality issues as well as risk and compliance issues, we will reorganize the purpose of the "Governance Promotion Meeting," which supervises the internal control and compliance initiatives of the Kobayashi Pharmaceutical Group. Moreover, we will also consider increasing the frequency of meetings in order to enable appropriate response to risk.

(B) Organizational Management with Integrity as a Code of Conduct

As stated in the Investigation Report, our interpretations 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. This may have been one of the reasons for the lack of promptness and smoothness in responding to this Matter.

Accordingly, even if an issue that is not clearly stated in the rules arises, we will promote "integrity management," where we continuously ask ourselves the questions: "What is usually correct?" and "Can I be proud of my actions with respect to my family and friends?" In other words, we intend to promote organizational management with integrity as a code of conduct.

In addition, we will establish a specialized department to promote integrity management. We will make our risk and compliance initiatives more effective and qualitative, rather than making initiatives for initiatives' sake.

(7) Improving External Communication and Information Distribution

In addition to the delay in announcing this Matter, there were also points to be improved thereafter, such as our approach to information disclosure, correspondence with administrative authorities, and communication with employees.

It is essential to promptly conduct the required administrative reporting in case of an emergency such as this Matter. From now on, we will not only do this, but also maintain close communication with governmental authorities even after we have conducted administrative reporting, and make sure to communicate information in a timely and appropriate manner and respond to instructions. In addition, we will ensure that we will distribute necessary information to customers in order to reassure them.

Accordingly, in order to carry out these measures effectively, we will reorganize our research and development departments and quality assurance departments to increase their expertise, and establish a system that allows us to obtain, aggregate, and distribute necessary information in a timely manner.

(8) Making Choices based on Resources

As various businesses and activities, including M&A, new business development, global expansion, and measures for SDGs, were expanding, Kobayashi Pharmaceutical had few opportunities to have company-wide discussions on the priorities of each activity and the allocation of necessary resources, etc.

On the other hand, once Kobayashi Pharmaceutical had started a business, even if the business fell into a situation where there was no possibility of its expansion and it fell in the red, we were unable to make decisions to withdraw or downsize such business, so to speak, continuing to manage the business only by "adding."

As a result, we had to allocate limited resources to a large number of projects. Under such circumstances, many resources were allocated to activities that contributed to profit growth, such as new product development and cost reduction, under the goal of continuous profit growth.

On the other hand, investment in matters that are less visible in terms of their contribution to business expansion, such as the preparation and revision of guidelines and rules, preventative quality control operations, and renewal of equipment for operation and maintenance at manufacturing sites, tended to be put off.

In this way, *monozukuri* (manufacturing) was carried out under conditions where resources ran short and employees at the site were overloaded.

From now on, the management team will, at the same time as taking these issues seriously and establishing a business portfolio strategy, secure appropriate personnel by giving priority to quality and safety. By deciding on what to discontinue and setting priorities, we will invest sufficiently in activities that do not directly lead to profits, but are fundamental to Kobayashi Pharmaceutical, such as legal compliance and quality control systems, as mentioned above.

4. Rebuilding a New Kobayashi Pharmaceutical through Unity

Kobayashi Pharmaceutical was managed by the members of a single family for a long time. As a result, many officers and employees tended to carry out their work in line with the intention of the founding family, under the direction and guidance based on the founding family's strong centripetal force.

Under such circumstances, peer pressure was easily exerted. Although a variety of opinions would be expressed at the GOMs in the early stages, ultimately the decisions were made in line with the intention of the founding family.

In this Matter, stronger doubts and objections should have been raised at the stage when there were successive reports on health damage. However, as a result of the fact that the President did not raise any strong objections to the response plan for this Matter reported by the members of the Pharmacovigilance & Consumer Relations Division or other divisions, the attendees at the GOMs also did not raise any doubts or objections in alignment with the President, and collective agreements were formed with ease.

We should never allow this Matter to happen again. To ensure this, we will review our relationship with the founding family as described above, and implement measures to eliminate homogeneity and strengthen diversity. Specifically, in terms of recruitment, assignment and evaluation, we will secure diverse human resources, assign them to each department, and train more senior personnel who can

evaluate and respect diversity.

In addition, we strongly determine to ensure that this Matter is never forgotten. We will designate "March 22nd," the day on which we announced this Matter, as "Quality and Safety Day (tentative name)" so that we will reflect on the opinions on this Matter from society as a whole, the causes for this Matter, and our responses to this Matter, etc. We will be sure to take actions every year to foster and strengthen a culture of "quality and safety first."

The employees of Kobayashi Pharmaceutical are people who can work with strong determination. Those employees and the management team will work together with a healthy loyalty, and contribute to society and endeavor to restore trust through unity with a spirit of "quality and safety first."

5. Summary

While we delayed the announcement of this Matter until March 22, 2024, there was the fact that our awareness of quality and safety and our existing systems were insufficient. In addition, during the course of the Matter we were unable to promptly and appropriately disseminate and share information with our customers and internally. Furthermore, even after March 22, there were aspects that needed to be improved in terms of information disclosure, administrative responses, and communication with employees etc. We have deeply reflected on these shortcomings.

We will promptly begin implementing and thoroughly execute these Reoccurrence Prevention Measures. Among these measures, we are aiming to implement those that involve internal organizational changes (such as the establishment of a new department) from January 2025 onwards.

We pledge to steadily implement these Reoccurrence Prevention Measures and to be reborn as a new company that can genuinely contribute to our customers and the world.

End