# Request for discontinuation of use of Red Yeast Rice related products and notice of voluntary recall (Second Report)

In connection with our press release "Request for discontinuation of use of <u>Red Yeast Rice</u> related products and notice of voluntary recall" dated March 22, 2024, KOBAYASHI Pharmaceutical Co., Ltd. (Head office: Osaka, Japan; President: Akihiro Kobayashi) hereby provides additional information on the following five points: 1. Long hold times for calls with the Health Consultation Centers; 2. Number of hospitalizations; 3. Manufacturing numbers of products that may contain unanticipated components; 4. <u>Red Yeast Rice</u> ingredients sold to B-to-B customers; and 5. Impact on performance.

## 1. Long hold times for calls with the Health Consultation Centers

With operations having started as of 17:00 on Friday, March 22, 2024, the <u>Red Yeast Rice</u> Health Consultation Center took calls from customers who feel any physical discomfort even on Saturday, March 23 and Sunday, March 24 as this is a matter we are taking very seriously and are committed to work with consumers on. That being said, we apologize that the lines are quite busy and callers are being put on hold for long periods of time. KOBAYASHI Pharmaceutical will devote ourselves to enhance the functionality of the Health Consultation Centers by increasing the number of available lines and consultation representatives.

#### 2. Number of hospitalizations

Based on information received through phone calls made to the Health Consultation Centers and other sources as of March 24, 2024, we have learned that some customers have been hospitalized with kidney problems.

Total number of hospitalized cases: 26 (not including hospitalizations for inspection purposes)

Number of cases we learned of before March 22 (already announced at the press conference): 6

Number of cases we learned of after March 22: 20

We are currently receiving calls from a number of customers, so please note that these figures are based on the information we possess at the present moment.

### 3. Manufacturing numbers of products that may contain unanticipated components

As announced in "Request for discontinuation of use of <u>Red Yeast Rice</u> related products and notice of voluntary recall" dated March 22, 2024, we conducted an ingredient analysis of Beni-koji Choleste-Help and the <u>Red Yeast Rice</u> ingredients used in it (manufactured by us) where we found that some of the <u>Red Yeast Rice</u> ingredients may contain components that we did not anticipate.

At the time of announcement on March 22, 2024, we had not inspected products for all manufacturing numbers, so we decided to voluntarily recall all <u>Red Yeast Rice</u> related products as a precautionary measure. We are working hard to conduct analyses, and we have at the very least completed our inspection of products manufactured in the last one-year period, summarizing those results in the report below. However, we have not been able to identify the exact ingredient nor the causal relationship between this product and experiencing kidney problems. Therefore, we are still recalling all products, regardless of manufacturing number.

Please see below for the manufacturing numbers of Beni-koji Choleste-Help that may contain unanticipated Red Yeast Rice related components.

Manufacturing numbers are indicated in the bottom-left corner of the back of the product.



Products sold at drugstores and on e-commerce sites: 14 types Manufacturing number: J3017, X3037, X3027, X3017, H3057, H3047, H3037, H3027, H3017, F3037, F3027, E3037, E3027, D3079

Products sold through our mail order service: 4 types Manufacturing number: X304, <u>H306</u>, G301, E301

Note: Hospitalized consumers have taken products with underlined manufacturing numbers.

### 4. Red Yeast Rice ingredients sold to B-to-B customers

We have received many inquiries in response to our statement in the press release dated March 22, 2024 that Red Yeast Rice ingredients sold to B-to-B customers (distributor: Kobayashi Pharmaceutical Value Support Co., Ltd.) are also subject to this voluntary recall, and the distributor is contacting suppliers to address the voluntary recall on an individual basis." In light of these inquiries, we hereby provide additional information concerning Red Yeast Rice ingredients sold to B-to-B customers.

For the Red Yest Rice ingredients sold to B-to-B customers, Kobayashi Pharmaceutical Value Support Co., Ltd., the distributor and our subsidiary ("KVS"), started to contact the

52 companies one by one that KVS distributes ingredients to on March 22 and asked corporate customers and their customers to refrain from selling and using the Red Yeast Rice ingredients. We also requested them to cooperate with us in taking corrective measures, including the collection of products using the Red Yeast Rice ingredients (including those still in inventory), and we will continue to provide information to B-to-B customers.

As of March 24, we have not received any report of kidney problems in connection with the products using the Red Yeast Rice ingredients sold by KVS to B-to-B customers.

The volume of the Red Yeast Rice ingredients manufactured by us in 2023 was 18.5 tons. Below we have listed the volume breakdown of the Red Yeast Rice ingredients used for our Beni-koji Choleste-Help and other products and the Red Yeast Rice ingredients sold to B-to-B customers.

- i. Red Yeast Rice ingredients used for our Beni-koji Choleste-Help and other products: 2.4 tons
- ii. Red Yeast Rice ingredients sold to B-to-B customers: 16.1 tons
  - a) 6.9 tons
  - the same Red Yeast Rice ingredients used in our Beni-koji Choleste-Help and other products
  - purpose of use: supplements, etc.
  - we have confirmed that some of them contain components that we did not anticipate as stated in the press release on March 22, 2024

Applicable items: 3P-D20, 3P-D M-11 Manufacturing number: 320-23B02R, 320-23907R, 320-23711R, 320-23404R, 320 - 23712R, 320 - 23308R

- b) 9.2 tons
- different type of Red Yeast Rice ingredients than those used in our Benikoji Choleste-Help and other products
- purpose of use: food, coloring, and flavor enhancement
- we have confirmed that none of them contain components that we did not anticipate

Applicable items: 3P-D1, 3P-D2, 3G-DTW, 1P-DK, 1G-D, 1G-WLK, 1G-WLK5, 5P-D

### 5. Impact on performance

The impact of this matter on the consolidated results for FY2024 is currently being carefully examined, and in the event that any information that should be disclosed arises, we will promptly disclose such information.