

October 4, 2002

To: Prefectural governors,
Mayor of designated cities, and
Mayor of special wards

Director-General of the Pharmaceutical and Medical Safety Bureau,
Ministry of Health, Labour and Welfare

Guidelines for Preventive Measures for Health Problems Caused by Health Foods and Unapproved/Unlicensed Pharmaceutical Products

Many cases of health problems caused by so-called dietary health foods have been reported, including cases of death, and there are concerns that similar incidents will repeatedly occur.

Considering such situation, the Ministry of Health, Labour and Welfare (MHLW) has decided to formulate the Guidelines for Preventive Measures for Health Problems Caused by Health Foods and Unapproved/Unlicensed Pharmaceutical Products. The guidelines are intended to set forth systems to prevent health problems caused by health foods and unapproved/unlicensed pharmaceutical products, and to also set forth measures to be taken to prevent further occurrences of health problems when they occur. As an immediate measure by the time of the formulation, the MHLW has issued the Points to Note for Prevention of Health Problems Caused by So-Called Dietary Health Foods. (Notice of the Director-General of the Pharmaceutical and Medical Safety Bureau, 医薬発 No.0828003, August 28, 2002).

This time, the Guidelines for Preventive Measures for Health Problems Caused by Health Foods and Unapproved/Unlicensed Pharmaceutical Products were prepared, as shown in the Appendix. The guidelines are notified as technical advice referred to in the provisions of Article 245-4, paragraph (1) of the Local Autonomy Act (Act No.67 of 1947). The heads of prefectures, designated cities, and special wards are requested to inform the relevant sections and organizations of the guidelines and make sure that necessary measures are properly implemented.

Note that the Points to Note for Prevention of Health Problems Caused by So-Called Dietary Health Foods (Notice of the Director-General of the Pharmaceutical and Medical Safety Bureau, 医薬発 No.0828003, August 28, 2002) is abolished.

Appendix

Guidelines for Preventive Measures for Health Problems Caused by Health Foods and Unapproved/Unlicensed Pharmaceutical Products

I Purpose

These guidelines describe measures that should be taken by prefectures, designated cities, and special wards (hereinafter, referred to as “prefectures, etc.”), as well as the MHLW, to prevent the occurrence of health problems caused by so-called health food (hereinafter, referred to as “health foods”) or unapproved/unlicensed pharmaceutical products purporting to be ‘health food’ (hereinafter, referred to as “unapproved/unlicensed pharmaceutical products”) and also to prevent further occurrences of health problems when they occur.

II Basic Understanding for Preventing Health Problems

For preventing health problems caused by health foods and unapproved/unlicensed pharmaceutical products (hereinafter, referred to as “health foods, etc.”), it is necessary to keep the following in mind.

1. Prevention of the occurrence of health problems

Persons who are engaged in preventing health problems must collect and evaluate the information on health foods, etc. on a daily basis, collaborate with relevant organizations, and work to implement preventive measures, such as providing information to residents.

If the possibility of the occurrence of health problems cannot be determined immediately, it is necessary to make efforts to plan and implement measures, always assuming the worst case.

2. Prevention of further occurrences of health problems when they occur

When it is suspected that, as a result of an investigation, there is a causal relationship between the health problems and the health foods, etc. for which complaints or consultations are made, to prevent further occurrences of the health problems, it is necessary to take measures, such as the announcement of the product name, stopping distribution, provision of health consultations, and recommendation for victims to consult a medical practitioner.

If the causal relationship between the health problems that occurred and the health foods, etc. is not apparent, or the possibility of further occurrences of the health problems

cannot be determined immediately because of uncertain information on the safety, it is necessary to make efforts to plan and implement measures, always assuming the worst case.

3. Prompt response through close cooperation between the department in charge of foods and the department in charge of pharmaceutical products

When a health problem occurs due to a health food, etc., it may be difficult to determine promptly which department should respond and which law should apply because it cannot be determined whether the causal substance is a food or a pharmaceutical product. However, to prevent further occurrences of health problems, it is necessary to take all available measures as soon as possible. Also, both departments in charge of foods and pharmaceutical products must work together. In particular, to take necessary measures under emergency conditions, it is critical that the person in charge of supervision exhibits excellent leadership.

4. Continuous improvement of measures by verifying measures taken in the past

Responsible departments of the MHLW and prefectures, etc. should regularly verify the measures taken for such health problems in the past and should, based on the verification results, work to improve the measures for the future.

III Measures in Normal Times

1. Prefectures, etc.

(1) Points to note when collecting information

Not only food sanitation inspectors and pharmaceutical affairs inspectors but also staff members of public health centers, such as doctors, pharmacists, public health nurses, registered dietitians, must always be on the lookout for the occurrence of health problems, for example, during complaint consultations and patient diagnoses.

Each public health center must work to grasp the information on health food manufacturers in its jurisdiction and ask the manufacturers to provide information when they have obtained information on the occurrence of health problems.

(2) Cooperation with relevant organizations

i. Cooperation with medical institutions

The prefectures, etc. must cooperate with medical institutions by informing doctors, pharmacists, registered dietitians and others (hereinafter, referred to as “doctors,

etc.”) of the following matters and asking for cooperation from doctors, etc. through local medical associations, pharmaceutical associations, and dietetic associations so that the information suspected to be related to health problems caused by health foods, etc. will be provided to public health centers.

- a. The fact that public health centers accept complaints and consultations on health foods, etc. and report the cases of health problems to the MHLW using the report form (Attachment).
- b. A request for the provision of information, including the name of the person who is suspected to suffer health problems associated with health foods, etc., causes of the suspected health problems, and results of medical diagnosis, to public health centers after obtaining the consent of the person in question.
- c. A request for cooperation in the investigation conducted by public health centers on cases of health problems caused by health foods, etc.
- d. The name and contact information of persons in charge of above investigation at public health centers.

ii. Cooperation with administrative agencies for consumer protection

Each public health center must continually exchange information on complaints about health foods, etc. with the consumer affairs center that has jurisdiction of the area by holding liaison meetings regularly and cooperate with the center to facilitate people who complain of health problems to consult the public health center.

(3) Information provision to residents

i. Information dissemination and awareness-raising

Through public health centers, etc., the prefectures, etc. must provide information, including the following matters, to residents and raise their awareness of the risk of health foods, etc.

- Occurrence status of health problems suspected to be caused by ingesting health foods, etc. in the past (e.g., product name, symptoms, number of reported victims)
- The fact that some so-called health foods contain ingredients that are not listed in the ingredient label
- When purchasing health foods, etc., it is necessary to be aware of potential risk of health problems, considering past occurrences.
- If symptoms have developed that are thought to be caused by the ingestion of

health foods, etc., it is recommended to consult a medical practitioner.

ii. Dissemination of complaint and consultation system

Making it known to residents that public health centers accept complaints and consultations on health foods, etc. from residents, the prefectures, etc. must encourage them to swiftly report to public health centers when they are suspected of suffering health problems.

(4) Supervision and guidance of unapproved/unlicensed pharmaceutical products

For unapproved/unlicensed pharmaceutical products, the prefectures, etc. must conduct supervision and guidance based on the Supervision and Guidance Manual for Unapproved/Unlicensed Pharmaceutical Products (Notice 医薬監麻発 No.333, March 27, 2001).

If the violation of the Pharmaceutical Affairs Act is suspected, according to the Guidelines for Pharmaceutical Surveillance and Guidance (Notice 医薬発 No.333, March 29, 2000), the prefectures, etc. must conduct on-site inspection and make the violator report necessary information, and then must take disciplinary actions for the violator, as needed. If the violation is flagrant, bring criminal charges against the violator.

2. Ministry of Health, Labour and Welfare (MHLW)

(1) Information collection and evaluation

The MHLW collects and evaluates, on a regular basis, necessary information promptly and precisely to prevent the occurrence of health problems caused by health foods, etc., based on the Guidelines for Food Poisoning Health Risk Management and the Guidelines for Pharmaceutical Products Health Risk Management, in principle.

In the process of collecting such information in accordance with these guidelines, if the Department of Food Safety¹ has collected the information on unapproved/unlicensed pharmaceutical products, such information is provided to the Compliance and Narcotics Division of the Pharmaceutical and Medical Safety Bureau². If the Pharmaceutical and Medical Safety Bureau (excluding the Department of Food Safety) has collected information on health foods, such information is provided to the

¹ The Department of Food Safety has been renamed to the Pharmaceutical Safety and Environmental Health Bureau.

² The Pharmaceutical and Food Medical Bureau has been renamed to the Pharmaceutical Safety and Environmental Health Bureau.

Office of Health Policy on Newly Developed Food of the Department of Food Safety.

The MHLW also collect information on health problems suspected to be caused by health foods, etc. that the National Consumer Affairs Center of Japan grasps.

(2) Information provision

i. Building of a database

The MHLW collects and analyzes information related to health foods, etc. in Japan and overseas, for example, information on cases of health problems, research reports, literature, and sales regulations including sales prohibitions. Such information is put into a database and provided to ordinary citizens and doctors, etc. via the MHLW's website.

ii. Health education

The MHLW enhances the dissemination of the right knowledge through the formulation of guidelines for healthy eating habits that lead to the sound mental and physical development.

(3) Management of relevant information

The Office of Health Policy on Newly Developed Food and the Compliance and Narcotics Division (hereinafter, referred to as "both sections") properly manage the information on premises of the determination of measures for health foods, etc. and on the reasons for the determination, etc., in order to continuously review the measures for health foods, etc. in a timely and appropriate manner.

IV Measures to Be Taken When Health Problems Occur

1. Prefectures, etc.

(1) Acceptance of consultation

- i. When a public health center conducts consultation on health problems related to health foods, etc., the center must listen carefully the details according to the investigation items in the report form (Attachment).
- ii. If the victim has already received a doctor's diagnosis, with the victim's consent, the health center concerned must contact the doctor to thoroughly ask about the victim's medical conditions and other conditions.
- iii. If the victim has not yet received a doctor's diagnosis, the health center concerned must recommend the victim to consult a doctor at a public health center or a medical institution.

(2) Investigations through hearing and ingredient analysis

- i. For the cases of health problems suspected to be caused by health foods, etc., given that the particularity of such health problems related to health foods, etc., the department in charge of foods and the department in charge of pharmaceutical products must, in principle, share the same information and conduct investigations in cooperation and in parallel, to prevent further occurrences of the health problems.
 - a. The department in charge of foods must conduct a hearing with doctors, etc., manufacturers, and distributors; and analyze the hazardous substances in such health foods as necessary.
 - b. If the cause of a health problem is thought to be pharmaceutical ingredients in light of past similar cases, the department in charge of pharmaceutical products must analyze the ingredients in question.

ii. Points to note when conducting an investigation

- a. Obtainment of products
Strive to obtain the product the person who is suspected of suffering health problems had ingested.
- b. Removal of products
In the removal of health foods, etc. that is conducted pursuant to the Food Sanitation Act, if the purpose of the removal is analyzing the pharmaceutical ingredients of the product in question, it must be done with the consent of the manufacturer, distributor, and other business operators.
- c. Cooperation with public health centers in other areas
If the manufacturers or distributors of the health foods, etc. subject to the investigation are located outside the jurisdiction of the public health center that received the consultations of health problems or located in another prefecture, the prefectures, etc. having jurisdiction of the public health center must cooperate with the public health center in the manufacturers' or distributors' location, such as by asking the prefecture, etc. concerned to cooperate in the investigation.
- d. Investigations on persons who may have ingested the health foods, etc. suspected to be the cause of health problems
If necessary, in addition to the persons who have reported their ingestion of health foods, etc. suspected to have caused health problems through the hearing investigation with them or the distributors, the prefectures, etc. must identify

persons who might have ingested the health foods, etc. and conduct investigations.

e. Ingredient analysis

At investigation, it is desirable, as needed, to conduct mutual support and information exchange including technical advice between national and prefectural institutes (National Institutes of Health Sciences and prefectural and municipal public health institutes).

If a public health center cannot analyze ingredients, the departments responsible for public health of the prefecture, designated city, or special ward concerned must conduct it under the coordination with each other.

- f. When an ingredient analysis has found that a cause substance is identified as a food or a pharmaceutical product, the department in charge of the substance in question must respond to the case in a unified manner. However, the department in charge of foods and the department in charge of pharmaceutical products must continue to exchange information on investigation results, etc.

iii. Points to note when making a conclusion

- a. It is essential to make a comprehensive and scientific conclusion on the obtained results. Be careful not to persist with a foreseen opinion nor make a wrong conclusion due to being confused by false reports.
- b. It should be noted that even the analysis result was negative, the cause may be estimated from the epidemiological findings or the results of the symptomatic observation.
- c. In making a comprehensive determination of the cause, the categorization of the causative food or the causative substance in the food should be clarified. Whether the categorization was confirmed by an epidemiological investigation or the ingredient analysis, or just by presumption, is also should be defined.

(3) Report to the Ministry of Health, Labour and Welfare (MHLW)

i. Report using the form

When conducting consultations on health problems related to health foods, etc., public health centers must prepare a report using the form (see Attachment) and submit it at the completion of each investigation via the supervisory department of the prefecture concerned (or via the city or special ward, when a case was handled by a city or special ward with a public health center. The same applies in this

section, (3) of IV). When the health foods, etc. are handled as foods, the report should be submitted to the Office of Health Policy on Newly Developed Food of the Department of Food Safety. When they are handled as pharmaceutical products, the report should be submitted to Compliance and Narcotics Division of the Pharmaceutical and Medical Safety Bureau. In preparing the report, note the following points in a through d. However, in the case of an emergency, such as the occurrence of severe health problems, the case must be reported immediately to the MHLW, even if the investigation has not been completed.

- a. For the results of the ingredient analysis, fill in the analysis items and the results in the column of “Investigation results on manufacturers, etc.”
- b. If the case is investigated as a food poisoning, state to that effect in the column of “Measures/Conclusions/Opinions, etc.”
- c. Report all consultation cases, unless the causal relationship between the product reported as suspected of being a causal product and the health problem has been clearly denied in the investigation results. For cases that are not to be reported, state to that effect in the column of “Measures/Conclusions/Opinions, etc.” and retain the report forms.
- d. In reporting, attach materials for the reference of the health foods, etc. in question, such as the samples of the label and the advertisement.

ii. Exceptions: when a case is treated as food poisoning

When a public health center judges a case as food poisoning caused by a health food, notwithstanding above i, the case must be handled as falling under the cases stipulated in IV-2-(2)- 工 of the Guidelines for Food Poisoning (Notice 環発 No. 214, July 13, 1964). In such a case, the health center must immediately report the case to the Inspection and Safety Division³ of the Department of Food Safety, Pharmaceutical and Medical Safety Bureau, MHLW, via the sanitation and hygiene supervisory department of the prefecture, using the appended form 1 of the guidelines, even if the number of victims is only one in the case in question.

(4) Measures to prevent further occurrences of health problems

As a result of an investigation, if a causal relationship is suspected between a health problem and the health food, etc. for which complaints or consultations have been made, the prefectures, etc. concerned must take necessary measures including the following to prevent further occurrences of the health problem.

³ The Inspection and Safety Division has been renamed to the Food Inspection and Safety Division.

i. Announcement of product name, etc.

Announce to residents the product name of the health food, etc. suspected to be the cause of a health problem for raising residents' awareness, where this measure is determined to be necessary to prevent further occurrences, for example, including a case that the relationship is suspected from the investigation results even when the causal relationship has not been fully elucidated.

ii. Measures to stop distribution

Conduct on-site investigations for manufacturers and distributors, and work to grasp the distribution status.

For the health foods, etc. that violate the related laws and regulations, take the following points into account, and provide necessary measures, such as guidance and administrative dispositions for manufacturers and distributors to stop the distribution of the products in question.

- For a product that has been confirmed to be a causative food, or that has a high probability of being a causative food, pursuant to the provisions of Article 22 of the Food Sanitation Act, make the business operator take measures, such as disposal.
- For unapproved/unlicensed pharmaceutical products, pursuant to the provisions of Article 70, paragraph (1) or (2) of the Pharmaceutical Affairs Act, make the persons who handle the pharmaceutical products in their business take measures, such as disposal and recall.

(5) Support for victims of health problems

If there is a possibility that, in the jurisdiction of a public health center, there are many other victims associated with a health food etc. that have caused health problems, the health centers must work to support them by taking the following measures.

i. Provision of health consultation

Develop a support system for the victims of the health problems, such as setting up a consultation counter for health problems within the jurisdiction. If necessary, provide the consulters with information about the properties and toxicity of the causal substance in question, based on the latest knowledge and information.

ii. Advice to consult a medical practitioner and information provision to the medical institution

Through the press, etc., call for the persons who ingested the health foods, etc. to consult a medical practitioner, and provide medical institutions and pharmacies

with information necessary for diagnosis, etc. on the causal substance of the health problems, including information on its properties and toxicity.

(6) Criminal charges

When it seems necessary to pursue liability, such as a case of malicious violation of laws, the prefectures, etc. must denounce to the prosecution.

(7) Retention of records

The prefectures, etc. must evaluate investigation results on incidents, and compile and retain the records. With the accumulation of the records, they must take measures to prevent the occurrences of similar cases in the future.

2. Ministry of Health, Labour and Welfare (MHLW)

(1) Information collection and evaluation

- i. Both sections mainly work to collect a wide range of information on health problems related to health foods, etc.
- ii. For a case of health problems suspected to be caused by the health foods reported from a prefecture, a designated city, or a special ward, if the judgment whether the cause substance is handled as a food or pharmaceutical product is different from that by other prefectures, etc., the Office of Health Policy on Newly Developed Food or the Compliance and Narcotics Division notifies the prefecture, designated city, or special ward concerned of that effect.
- iii. If a health food, etc. imported for sale are suspected to be the cause of a health problem, the Office of Health Policy on Newly Developed Food collects information on the import notification of the food from the quarantine concerned via the Office of Quarantine Station Administration, using mainly the Food Automated Import Notification and Inspection Network System (FAINS). Also, the Office collects information on the food in question through prefectures, etc. In addition, the Office works to grasp overseas information, including the occurrence of similar cases of the health problem, as well as the production, processing, and distribution status of the food in question, through overseas diplomatic establishments and the Ministry of Foreign Affairs of Japan.
- iv. Both sections, if necessary, hold meetings of experts mainly from national research institutes and hear opinions for each case, regarding the analysis and evaluation to determine whether the product name and other items should be announced, from the viewpoints of epidemiology. However, in the event of an emergency, hearing

of the opinions from the experts is not required for prompt provision of information.

(2) Cooperation with relevant sections

To collect, evaluate, and share the information on health foods, etc., and to plan and coordinate measures for prevention of health problems, the MHLW holds liaison meetings constituted of the directors of MHLW's relevant sections.

(3) Consideration of necessary measures

If a health problem is suspected to occur based on the information from public health centers, the MHLW immediately decides what measures should be taken to prevent further occurrences of the health problem.

When planning measures for the cases of health problems, relevant bureaus and divisions work in cooperation, such as by holding liaison meetings.

Both sections hold meetings of the Pharmaceutical Affairs and Food Sanitation Council as necessary, and hear opinions for necessary measures from experts' viewpoints.

(4) Information provision

i. Information provision to prefectures, etc.

Both sections provide prefectures, etc. with information, in writing, on the cases of health problems suspected to be caused by health foods, etc. Also use electronic media to response promptly.

ii. Information provision to medical institutions

Both sections provide medical institutions with information via the prefectures, etc. concerned and under the cooperation of relevant organizations, such as those to which the institutions are affiliated.

For urgent information provision, utilize appropriate media including the MHLW's website.

iii. Information provision to citizens

Both sections provide citizens and relevant parties with information on the cases of health problems suspected to be caused by health foods, etc. utilizing various media including the MHLW's website and brochures, and with cooperation from the news media, if necessary.

Report Form on Health Problems Related to Health Foods, etc.

Date of submission (Month/Day/Year)

_____ Prefecture / City / Ward

Type of food and product name		Date of reception (Month/Day/Year)	
Packaging form		Quantity	
Expiration date or best-before date		Storage condition	
Name and address of the manufacturer / importer	Full name		
	Address	Tel.:	
Name and address of the seller	Full name		
	Address	Tel.:	
Reported by:	Person who suffers health problems ("victim") / the family of the victim / medical institution / other: _____		
Overview of the report		The age and the sex of the victim	Age: _____ (Male / Female)
Victim's health condition	Daily dose of the product	Number of capsules/tablets each time: Number of times per day: Total number of capsules/tablets per day: _____	
	Purpose and the duration of consumption of the product		
<p>The victim's consent to the public health center's investigation against doctors, etc.: Yes / No</p> <p>Presence or absence of the product: Presence / Absence</p> <p>The source of purchasing the product: _____</p>			
Doctors' opinions	Describe main symptoms; ingestion history of other pharmaceutical products; diagnosis/examination results; medical treatment progress; and degree of the causal relationship between the ingestion of the food and main symptoms, and reasons for the judgment.		
Medical institution	Date of confirmation (Month/Day/Year)		
	Name of medical institution		
	Address and phone number	Tel.:	
Investigation results on manufacturers, etc.	Describe the sales volume of the food, distribution routes, presence of other complaints, results of pharmaceutical ingredient analysis, etc.		
<p>Whether the manufacturer had received similar complaints: Yes / No. If "Yes," attach the written overview.</p>			
Measures/Conclusions/Opinions			