

## Section 10

### Promotion of Measures for Safety and Security of People

#### 1 Response to health damage caused by drugs/medical devices

##### (1) Response to the drug-induced hepatitis lawsuit

Relief of sufferers based on the “Act concerning Special Measures for Relief from Hepatitis C Infection”

Pursuant to the provisions of the “Act concerning Special Measures to the Payment of Benefits to Relief Sufferers from Hepatitis C Infection caused by Specific Fibrinogen Products and Specific Coagulation Factor IX Blood Products” (enacted on January 2008, and hereinafter referred to as the “Act concerning Special Measures for Relief from Hepatitis C Infection”), benefit has been offered to the sufferers after confirmation at the courts of their Hepatitis C virus infection caused by administration of specific products. (As of July 1, 2010, compromises have been concluded with 1,519 people, and the number of people who receive benefit was 1,463 people).

The Ministry of Health, Labour and Welfare is making an effort to publicize the concept of the law as well as calling for people to take Hepatitis virus examinations who were possibly administered fibrinogen products or Coagulation Factor IX blood products through disclosing the names of the medical institutions that the products were supplied to.

The payment system and procedures to claim benefit have been publicized in accordance with the enforcement of the law for example through posting Q&A on the websites of the Ministry of Health, Labour and Welfare. Taking into account the inquiries received from various from various quarters over the past two years since the enforcement of the “Act concerning Special Measures for Relief from Hepatitis C Infection”, revisions will be made, and publication will be carried out more carefully for the people eligible for the benefit.

##### 2) “Study Group on Examination of Hepatitis C virus infection caused by use of Hepatitis C virus-tainted blood products and Prevention of the Recurrence”

In accordance with the “Act concerning Special Measures for Relief from Hepatitis C Infection”, the government recognized its liability for that it caused great damage to the sufferers and could not prevent its spread, and offered sincere apologies to them and their bereaved families. In addition, in view of the reflection on this case, the government made a promise to renew awareness of precious life and make the maximum effort to prevent any recurrence of suffering to people’s health caused by drugs by the “Basic Agreement” signed by the Minister of Health, Labour and Welfare, the plaintiff, and the counsel on

January 15, 2008.

Having made aforementioned basic agreement and discussions among the Minister of Health, Labour and Welfare, the plaintiff, and the counsel, the Ministry of Health, Labour and Welfare established a "Study Group on Examination of Hepatitis C virus infection caused by using of Hepatitis C virus-tainted blood products and Prevention of the Recurrence" (hereinafter referred to as the Study Group on Examination) on May 23, 2008.

The Study Group on Examination was originally planned to be held for one year. The Group member themselves, however, decided to extend and ensure through discussion. As a result, the discussions continued two years. Intensive discussions took place focusing on the reinforcement of post-marketing safety measures as an urgent. As a result of the discussions, the interim summary was compiled on July 31, 2008. Since October 2008, the Study Group on Examination discussed on prevention of any recurrence of suffering to people's health caused by drugs in consideration of the issues extracted from the incidence of Hepatitis C virus infection, and submitted "The First Proposal" on April 30, 2009 as the destination of the discussions held in FY 2008. In FY 2009, discussions were made focusing on the issues which were not covered in FY 2008 in addition to the discussions based on the examination on the incidence of Hepatitis C virus infection. The "Final Proposal" was issued on April 28, 2009.

The Ministry of Health, Labour and Welfare has renewed the awareness of precious life and declared to make the best and utmost efforts to prevent recurrence of suffering to people's health caused by drug-induced sufferings or drugs. In addition to sincerely responding to the final proposal, the Ministry will take measures quickly and steadily starting with the ones available.

### 3) Issue of Fibrinogen data

Data, including a table of 418 cases related to the administration of fibrinogen products, submitted by Mitsubishi Pharma Corporation (at the time) in response to an order to submit a report was published with masking (private information painted black) in 2002. The Ministry of Health, Labour and Welfare, however, discovered data with the names of 2 patients that had not been masked in basement storage on October 19, 2007.

The Minister of Health, Labour and Welfare ordered an investigation of this issue and its background. The investigations, conducted by the "Project Team for Investigation on the Fibrinogen Data Issue and its Background" (hereinafter referred to as the "Investigation Team"), revealed that data was very improperly transferred and managed and no discussions were made within the Ministry on notifying the 418 patients by identifying the individuals using the data. The Investigation Team reported that since the Ministry failed to

think about notify the patients, “as an organization in charge of issues concerning people’s lives and health, the Ministry should accept the serious criticism in its entirety, that the Ministry should realize what should be done for people suffering with Hepatitis from the viewpoint of the patients.”

In response to this report, the Ministry of Health, Labour and Welfare is making the effort to appropriately manage documents within the Ministry. In addition, the Ministry is making their best effort with measures where people can take examination/treatment for Hepatitis as early as possible through disclosing the names of the medical institutions that fibrinogen products and Coagulation Factor IX blood products were supplied to.

(For details, please refer to Section 2-3 Chapter 1 in Part 1)

## (2) HIV/CJD Problems

### 1) Compromises and confirming letters concerning lawsuits regarding HIV problem and CJD problem

Hemophiliacs had filed compensation lawsuits for damages arising from HIV infections caused by blood products against the government, drug manufacturers and these compromises were concluded on March 29, 1996. And sufferers who had infected by CJD through human dry dura known as “Lyodura” had filed compensation lawsuits for damages against the government, drug manufacturers. A compromise of these lawsuits was concluded on March 25, 2002.

In confirming letters concerning these compromises, the Ministry of Health, Labour and Welfare had stated that it would sincerely and seriously accept the views of the court. Furthermore, it realized the serious responsibility of the Ministry for the spread of HIV infection among hemophiliacs and the CJD infection that resulted from the transplantation of the human dry dura of “Lyodura”, as well as for the terrible harm that resulted, which was pointed out in the letters. It also stated that the Ministry wholeheartedly apologized to the sufferers, including the plaintiffs having serious mental and physical damage, and the fact that they had been forced into an extremely serious situation.

The Ministry of Health, Labour and Welfare then made a firm promise to make an effort to investigate the cause of these incidents and to confirm what improvements had been made. It also made a promise that Ministry of Health, Labour and Welfare would make the best efforts to prevent any recurrence of suffering to people’s health caused by drugs, based on the recognition of their great responsibility to provide safe and effective drugs to the people and to protect people’s lives and health from adverse drug effects and adulterated drugs.



### Monument of Oath

Taking preciousness of life at heart, we hereby declare that we will make our best effort to secure safety and efficacy of drugs to prevent recurrence of thalidomide, SMON disease, HIV infection and other tragic suffering caused by drugs.

### 2) Promotion of various permanent measures

The Ministry of Health, Labour and Welfare is taking the following permanent measures that were based upon compromises reached in the HIV and CJD lawsuits.

#### ① Upgrading of medical care system

The Center for AIDS treatment, Research and Development was founded at the International Medical Center of Japan with the aim of improving medical care standards for AIDS in respective regions and to correct any regional differences. In addition, regional-block core hospitals were established in 8 districts, which are there to secure the appropriate medical treatment, along with model hospitals for AIDS treatment. In the mean time, a system to send at-home medical care support teams consisting of specialized doctors stationed in respective prefectures was established to secure the stable recuperation of CJD and other patients, as well as a system of technical support for doctors treating CJD patients.

#### ② Support for patients and the bereaved

Counseling activities for the bereaved are conducted with the aim of relieving the mental distress of bereaved whose children, spouses, etc. was lost to HIV infection caused by blood products. In FY 2010, the counseling desk was to be established to help the bereaved to smoothly receive necessary medical care. In the meantime, support is being offered through support network activities, particularly through telephone counseling conducted by families whose patients was lost to CJD, with the aim of improving the welfare of patients and their families. Efforts are also being made to eliminate any prejudice and discrimination against the people that are infected with HIV and so on.

### ③ Condolence activities

As a measure of consoling the spirit of the sufferers, an “Oath Monument” was set up in the front garden of the Ministry of Health, Labour and Welfare (August 1999), in declaring the determination to do its best efforts to secure the safety and efficacy of drugs and to prevent any recurrence of miserable incidents like the HIV infections caused by drugs.

#### (3) The Relief System for Sufferers from Adverse Drug Reactions/The Relief System for Sufferers from Diseases Infected from Biological Products

Drugs are indispensable for the people to maintain and develop their health, but health damage caused by adverse reactions in spite of proper use of drugs cannot be completely prevented. At times, drugs cause severe health damage. Accordingly, in order to provide prompt and simple relief, the Relief System for Sufferers from Adverse Drug Reactions was established in May 1980 financed by contributions from pharmaceutical firms. In FY 2004, the Relief System for Sufferers from Diseases Infected from Biological Products was launched targeting health damage caused by infection, etc, in spite of proper use of biological products.

Under the Relief System for Sufferers from Adverse Drug Reactions, relief benefit has been paid to about 6,900 persons (at the end of FY 2008) since its foundation 30 years ago, and the number of benefit payment has grown in recent years. While measures have been taken for users' convenience, for instance through extension of deadline for claims, additional measures will be taken for better publication of the system focusing on medical professionals including medical doctors and pharmacists so that the system can be properly used when necessary.



(Example of advertisement)

## 2 Measures for preventing drug abuse

The number of drug offenders arrested was 15,417 in 2009. And the number of

methamphetamine offenders increased to 11,873 from the previous year, accounting for a little fewer than 80% of all drug offenders. The number of cannabis offenders was a record high at 3,087, and the situation of drug abuse in young generation especially those in their twenties appeared rampant and continued grave situation.

With regard to measures to prevent drug abuse taken by the government, the “Headquarters for the Promotion of Countermeasures to Drug Abuse” (changed the name to the “Promotion Council for Countermeasures to Drug Abuse” in December 2008 as a subordinate organization of a Cabinet meeting on Crime Countermeasures) formulated “The 3rd 5-Year Strategy to Prevent Drug Abuse” \*1, and comprehensive measures have been promoted in close cooperation with related ministries and agencies.

For the measures to prevent drug re-abuse, it is very important to create an environment where society does not accept drug. In view of this, the Ministry of Health, Labour and Welfare have carried out effective activities such as national campaigns like the “‘No, Absolutely No!’ public awareness Promotion Campaign” and dispatching of “caravan cars for drug abuse prevention” to schools all over Japan. Since drug abuse by juveniles has become a serious issue, enlightenment books focusing on cannabis/MDMA have been distributed to the students in their first year of middle school. Additionally, since FY 2009, enlightenment books specializing in cannabis and stimulants have been published and distributed to the students in their 3rd year of high school. Moreover, enlightenment activities have been implemented intensively on harmful and illegal\*2 aspects of cannabis.

As the measures to prevent drug re-abuse, consultation programs for drug abusers themselves and their families and the class for their families have been provided in health centers and local mental and welfare centers.

The control of drug offences has been implemented at the Narcotics Control Departments in Regional Bureaus of Health and Welfare (8 departments, 1 branch office and 3 annexes nationwide). The recent drug offences have become complicated and shrewd ranging from organized smuggling and illicit sales by organized crime group and drug trafficking organizations made up of foreigners including the Iranians, to trafficking over the cell phone or the Internet. In order to take countermeasures against them and to strengthen control of drug offences, the structure for investigation has been enhanced by increasing narcotic control agents and cooperation with related organizations has been promoted. As the measures for trafficking on the Internet, control for buying and selling hemp seed has been strengthened.

Substances of abuse not-controlled under the Narcotic Control Act and other legislation for drug control not only damage the health of abusers but also cause harm to public health as they can lead to narcotics or other illicit drugs being abused. Thus, they are designated

as designated substances\*5 controlled by the Pharmaceutical Affairs Act. In FY2009, six substances including three substances of the synthetic cannabinoids contained in the products such as “spice” were added to the designated substances (enforced on November 20, 2009. As of January 2010, 46 substances are designated as designated substance). Furthermore, enlightenment activities concerning designated substances have been conducted, for example by including their dangerous aspects in the aforementioned enlightenment books (for students in their first year of middle school) in addition to procurement investigations. Moreover, efforts are being made to impose further rigorous controls, designating substances of narcotic as soon as they have been validated to have dependency and other psychotoxicity.

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\*1 “The 3rd 5-Year Strategy to Prevent Drug Abuse”

<http://www8.cao.go.jp/souki/drug/sanzi5-senryaku.html>

\*2 Information on cannabis:

The Ministry of Health, Labour and Welfare

<http://www.mhlw.go.jp/bunya/iyakuhin/yakubuturanyou/index.html>

\*3 Measures to prevent drug re-abuse:

The Ministry of Health, Labour and Welfare

<http://www.mhlw.go.jp/bunya/iyakuhin/yakubuturanyou/index.html>

\*4 Narcotics Control Departments in Regional Bureaus of Health and Welfare:

<http://www.nco.go.jp/index.html>

\*5 Designated substances

The Ministry of Health, Labour and Welfare

<http://www.mhlw.go.jp/bunya/iyakuhin/yakubuturanyou/index.html>

3 Promotion of safety measures and establishment of systems for early provision of pharmaceuticals and medical devices

(1) Safety measures for pharmaceuticals and medical devices

Since pharmaceuticals and medical devices basically provide medication for patients by having some effect on human bodies, they do cure diseases as expected, while on the other hand, it is unavoidable to cause unexpected adverse drug reactions or medical device adverse effects. Pharmaceuticals and medical devices are allowed on the market after they are evaluated on both their effectiveness and safety based on the data including

clinical trials for obtaining approval from the Minister of Health, Labour and Welfare, as it is important to balance effectiveness and safety. However, safety information obtained through clinical trials before approval is limited. So, it is necessary to accurately collect information on adverse drug reactions and medical devices adverse effects after marketing, then to analyze and evaluate that information, and to take safety measures for pharmaceuticals and medical devices promptly based on that analysis and evaluation.

#### 1) Report system for adverse drug reactions

In accordance with the Pharmaceutical Affairs Act, information on post-marketing adverse drug reactions and medical device adverse events is reported from marketing authorization holders and medical professionals to the Minister of Health, Labour and Welfare. When the marketing authorization holders of pharmaceuticals and medical devices find out the occurrence of diseases that are suspected of being induced by adverse drug reactions and medical device adverse effects, they must report that information to the Minister of Health, Labour and Welfare. Medical professionals such as physicians, dentists, and pharmacists are also required to report any such information to the Minister of Health, Labour and Welfare in accordance with the “Pharmaceuticals and Medical Devices Safety Information Report System”. In FY 2008, approximately 35,000 cases of adverse drug reaction and around 7,000 cases of medical device adverse effects, based on the Pharmaceutical Affairs Act, were reported annually.

In addition, marketing authorization holders of pharmaceuticals and medical devices are obliged to conduct early-phase post-marketing surveillance on those products that require careful verification of safety such as newly approved products. They must also provide information of rational use of pharmaceuticals and medical devices and promptly detect occurrence of serious drug adverse reactions and medical device adverse effects by, for example, periodically visiting medical facilities.

#### 2) Evaluation and provision of information on adverse drug reactions and medical device adverse effects

The Ministry of Health, Labour and Welfare conducts immediate and appropriate evaluations of information on adverse drug reactions and medical devices adverse effects reported by marketing authorization holder and related medical professionals in cooperation with the Pharmaceuticals and Medical Devices Agency (PMDA), and implements safety measures based on the results of the evaluations. In particular for urgent and important information, the Ministry orders marketing authorization holders to distribute emergency safety alert information (so-called a doctor letter) in order to promptly



inform to medical institutions. In addition, information such as revision of instruction for use is provided through the monthly publication of “Pharmaceuticals and Medical Devices Safety Information”.

### 3) Prediction- and Prevention-Oriented Active Safety Measures

In addition to these passive safety measures, i prediction- and prevention-oriented active safety measures are being enhanced and strengthened in cooperation with related academic societies, medical facilities, and marketing authorization holders. In order to detect and deal with patients suffered from serious adverse reactions in early phase, the Ministry have edited and provided “Manual for Detection and Treatment of Serious Adverse Reactions by Symptom” that summarizes early symptom, detection and medication in collaboration with related academia since FY2005.

In addition, “Japan Drug Information Institution in Pregnancy” established the National Center for Child Health and Development collects information of effect of drugs on pregnant women and fetus through consultations with pregnant women who are worried about effects of medicines taken during pregnancy.

Furthermore, the PDMA has provided information for medical professionals, patients and their families by providing reports on adverse drug reactions reported from marketing authorization holders and “Patient Medication Guide” about drugs with information required special attention for patients prepared by drug marketing authorization holders since January 2006 through its website (<http://www.info.pmda.go.jp>) (Chart 2-2-10 in Section 2, Chapter 2, Part 1). In addition, “Information Distribution Service for Pharmaceuticals and Medical Devices” is provided on this website so that information and notification on safety measures for pharmaceuticals, etc. can be promptly and accurately obtained (Chart 2-2-9 in Section 2 Chapter 2 Part 1).

## (2) Speeding up approval review of pharmaceuticals and medical devices

### 1) Measures to promptly provide pharmaceuticals and medical devices

While the development of pharmaceuticals and medical devices is making rapid progress, it has been pointed out that pharmaceuticals and medical devices used abroad are not being made promptly available in Japan. It is expected to provide safe and effective drugs and medical devices to people in a timely manner.

Under this circumstance, measures for faster and better review will be implemented aiming for reducing the time to launch a new drug by 2.5 years based on the “Five-Year Strategy for Creation of Innovative Pharmaceuticals and Medical Devices” formulated jointly by the Ministry of Health, Labour and Welfare, the Ministry of Economy, Trade and

Industry, and the Ministry of Education, Culture, Sports, Science and Technology in April 2007 (and revised on May 2008 and February 2009). Concerning medical devices, measures will be taken to speed up and improve the quality of reviews by reducing the period required to grant approval by 19 months based on the “Action Program for Speeding Up Approval Review of Medical Devices” (formulated in December 2008).

More concretely, the following measures will be implemented: a) doubling the number of pharmaceutical reviewers and improving the quality (increase of 236 staff members over 3 years from FY 2007), b) clarifying the review processes and standards and improving implementation of GCP (Good Clinical Practice) \* 6, c) Establishing the consultation system for clinical trials for handling every consultation in a timely manner, d) discussions on the possible introduction of parallel scientific advice program for global clinical trials between regulators of Japan, the United States, and Europe, e) tripling the number of reviewers of medical devices and improving the quality (increase of 69 staff members over 5 years from FY 2009), f) clarifying the review standards of medical devices, and g) improving implementation of medical device GCP.

#### 2) Discussion on unapproved drugs/off-label drugs of high medical necessity

The “Study Group on Unapproved and Off-label Drugs of High Medical Need”, comprising of experts, started from February 2010. The Study Group evaluates the medical necessity of domestically unapproved drugs and their indications. The Study Group also assesses the applicability of the application based on well-known data (a method of application for approval without conducting additional clinical trial for the drug whose efficacy and safety is sufficiently scientifically-proved) as well as validates the industry view on the trials required for the application of the drug. The results will facilitate development of the drugs by related pharmaceutical firms.

#### 3) Discussion on early introduction of medical devices of high medical need

The “Study Group on Early Introduction of Medical Devices etc. of High Medical Need” (hereinafter referred to as the “Study Group on Need”) is held to discuss the early introduction of domestically unapproved or off-label use of medical devices and in-vitro diagnostics (IVDs). The study group has met 12 times to date and selected 33 types of prioritized medical devices. Discussions are being made on concrete measures for early introduction of these products. Among them, 15 types of medical devices were approved as of the end of June and provided to the medical practice sites. Early introduction of medical devices and IVDs of high medical needs will be promoted in the future and will include making additional selection of products to be discussed by the Study Group.

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\*6 GCP stands for Good Clinical Practice and refers to implementation standards for clinical trial.

\* 7 “Five-Year Strategy for Creation of Innovative Pharmaceuticals and Medical Devices”

<http://www.mhlw.go.jp/houdou/2009/03/h0305-1.html>

Chart 2-10-1 Information Supply in accordance with the Degree of Risks

Risk category	Specialists in charge	Active information supply even without question from purchasers	Response when consulted by purchasers
First-class OTC drugs	Pharmacists	Necessary information for proper use should be provided in writing.	Mandatory
Second-class OTC drugs	Pharmacists or registered sales persons*	Effort should be made to provide necessary information for proper use.	
Third-class OTC drugs		Not required	

\* Registered specialists who passed the examination carried out by the governor of prefecture to confirm qualification, which has been launched in accordance with the revision of the Pharmaceutical Affairs Act this time.

### (3) Revision of sales system for over-the-counter drugs

#### 1) Summary of revision of sales system for over-the-counter drugs

To cope with the changing environments surrounding over-the-counter drugs in recent years including changes in people’s consciousness and progress being made in separating dispensing from medical practice, the “Act to Amend the Pharmaceutical Affairs Act” (hereinafter referred to as the “Revised Pharmaceutical Affairs Act”) was promulgated on June 14, 2006 to revise the entire over-the-counter drug sales system.

Specifically, the revision aimed at establishing a system and environment for sales of over-the-counter drugs, for example through categorization of over-the-counter drugs into three classes and information provision by specialists in accordance with degree of the risks (Chart 2-10-1).

Regarding the Revised Pharmaceutical Affairs Act, the designations of the risk categories were executed on April 1, 2007 and an examination system regarding registered sales persons was implemented in April 1, 2008, and the law was entirely enforced in June 1, 2009.

#### 2) Contents of sales system for over-the-counter drugs

##### ① Designation of risk categories

Concerning designation of risk categories, a notification was promulgated on March 30,

2007 to designate First-class OTC drugs\*8 and Second-class OTC drugs \*9. This classification of over-the-counter drugs calls for efforts to be made in the collection/evaluation of the up-to-date information on their appropriate use and will be revised as required.

## ② Examination system regarding registered sales persons

The “Study Group on Formulation of Guidelines to Execute Registered Sales Person Examination” was held to discuss the scope of test papers and execution schemes for the examination and compiled a report in June 2007. 1 2 In consideration of this, the “Ordinance to Amend Enforcement Regulations of the Pharmaceutical Affairs Act was promulgated on January 31, 2008, and has been enforced in each prefecture starting in FY 2008.

A total of 58,715 applicants passed the Registered Sales Person Examination in FY 2008 (with the number of applicants of 91,024 and the pass rate of 64.5%).



Poster to publicize the sales system for over-the-counter drugs

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\*8 “First-class OTC drugs” refer to: ① drugs whose adverse effects could cause health damage to the degree that might disturb daily life and have been designated by the Minister of Health, Labour and Welfare as the ones that require special attention for the usage ; and ② drugs whose active ingredients are distinctly different from those of the drugs whose production and sales have been approved but not passed a certain period of time after obtaining an approval.

\*9 “Second-class OTC drugs” refer to those whose adverse effects could cause health damage to the degree that might disturb daily life (excluding First-class OTC drugs) and have been designated by the Minister of Health, Labour and Welfare.

### ③ Establishment of system and environment for sales of over-the-counter drugs

The “Study Group on Establishment of System and Environment Related to Sales of Drugs” was held, and a report was compiled in July 2008. In consideration of this, the “Ordinance to Amend Enforcement Regulations of the Pharmaceutical Affairs Act” (hereinafter referred to as the “Amended Ordinance” was promulgated on February 6, 2009 (Chart 2-1022).

In consideration that various opinions were gathered through the public comment for the aforementioned ordinance, a “Study Group on Smooth Implementation of a New Sales System for Pharmaceuticals” was held (7 meeting by May 2009). Taking into account the discussions made at this Study Group and aiming at taking provisional measures for the cases that purchasing drugs at pharmacies/drug stores is difficult; the “Ordinance to Amend the Ordinance to Amend Enforcement Regulations of the Pharmaceutical Affairs Act” was promulgated on May 29, 2009 (Chart 2-10-3).

### 3) Informing and enhancing of the sales system for over-the-counter drugs

#### ① Publication of the system

In addition to launching the special site \*11 on the official website of the Ministry of Health, Labour and Welfare, posters and leaflets are published and distributed nationwide through prefectures.

In addition, dissemination and enlightenment events for the new system were carried out during the “Drugs and Health Week” (which is carried out every year from October 17 to October 23) and at the “Children's day for visiting Kasumigaseki.”

#### ② Survey for the status of sales system for over-the-counter drugs

Since FY 2009, the survey has been carried out targeting pharmacies and stores nationwide with general consumers as investigators in order to check whether: a) new sales system for over-the-counter drugs has been established; and b) information are properly provided in accordance with the system.

### (4) Improving the quality of pharmacists and enhancing the role of pharmacy

#### 1) Improving the quality of pharmacists

It has become necessary to foster high-quality pharmacists in order to meet social demands being made in recent years such as promoting appropriate use of drugs in terms of the advance of medical technologies and the progress in separation of dispensing from medical practice. It is critical to enhance the quality of pharmacists through improving

pharmaceutical education at universities and life-long learning after graduation.

Chart 2-10-2 Main Points in the Amended Ordinance

- OTC drugs should be sold face to face by specialists, or by general sales persons under the supervision/instruction by the specialists
- Information on First-class and Second-class OTC drugs are provided face to face by specialists
- Mail-order sales is only available for Third-class OTC drugs\*10
- OTC drugs should be displayed by risk category

Chart 2-10-3 Transitional measures for mail-order sales of drugs etc.

- Mail-order sales of Second-class OTC drugs are available until May 31, 2011 for the following cases:
- when they are sold to the residents of isolated islands without any pharmacies/drug stores; and
  - when the same pharmacy/drug store sells the same drugs to those who had purchased the drug before the enforcement of the amended Ordinance (June 1, 2009) and were recognized as having continuously used the drug at the time of enforcement.

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\*10 “Third-class OTC drugs” refer to OTC drugs other than First-class and Second-class OTC drugs.

\* 11 The Websites for the sales system for the over-the-counter drugs

<http://www.mhlw.go.jp/bunya/iyakuhin/ippanyou/index.html>

(The websites can be accessed via the following links: The Ministry of Health, Labour and Welfare: <http://www.mhlw.go.jp/> → “Important Information” → the banner of the system)



Aiming at developing high-quality pharmacists, the education course at universities fostering pharmacists was extended from 4 years to 6 years so that they can foster practical abilities related to clinical affairs. As a result, graduates that have completed the 6-year school education course are qualified to take the National Examination for Pharmacists in 2006.

In 2012, the National Examination for Pharmacists will be launched, which responds to the revised educational curriculum due to the introduction of the 6-year pharmacy education system. Accordingly, in January 2010, the Ordinance for Enforcement of the

Pharmacists Act was revised, and the subjects of the new National Examination for Pharmacists were decided. Efforts will be continuously made to establish the question standards for the new examination system.

As part of the establishment of the system to accept on-the-job training program under the 6-year pharmacy education system, training program was carried out to develop certified pharmacists for on-the-job training. About 1.1 million pharmacists have been certified. In addition, specific field training on cancer drug therapy has been conducted since FY2006 in order to train pharmacists specialized in cancer with advanced knowledge and skills. Furthermore, the pharmacists who are imposed administrative sanctions discussed at the Medical Ethics Council have been obliged to take reeducation program since April 2008.

## 2) Enhancement of roles of pharmacies and promotion of separation of dispensing from medical practice

The “Act to Amend the Medical Care Act for Establishment of the System to Provide High Quality Medical Care” was enacted in 2006 to enhance the functions of pharmacies so that pharmacies can further contribute to community medical care. Based on this law, pharmacies were positioned as medical care provision facilities in April 2007, and are now expected to make contribution as bases for supplying pharmaceuticals under the regional medical care plan.

In addition, efforts are being made to promote the separation of dispensing from medical practice with aim of ensuring the appropriate use of drugs. In FY 2009, the number of prescriptions issued by external pharmacies was approximately 690 million. The rate of separation was estimated at 59.1%, of which increase of 1.4 points from the previous year (according to the “Assumption of prescription receiving ratio in FY 2009” issued by the Japan Pharmaceutical Association).

It is necessary to continuously promote a high quality system based on the medical care plan, etc. in accordance with the actualities of respective regions. Accordingly, in order to enlighten the appropriate use of pharmaceuticals and to provide the nation with information on drugs, the website “Online Drug Information \*12” has been launched since FY 2008 on the website of the Ministry of Health, Labour and Welfare.

In addition, efforts have been made to improve the quality of separation of dispensing from medical practice through the project to collect and analyze “hiyari-hatto cases” to secure medical safety at pharmacies. (Please refer to the column “Efforts to improve medical safety - the project to collect and analyze “hiyari-hatto cases.”)



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\*12 Online Information on Drugs

<http://www.mhlw.go.jp/bunya/iyakuhin/okusuri/index.html>

\*13 Japan Council for Quality Health Care (JCQHC)

<http://www.yakkyoku-hiyari.jcqhc.or.jp>

## Column

Roles of pharmacy for in-home medical care /in-home long-term care

Separation of dispensing and prescribing functions that patients bring prescription to pharmacies to take medicines after taking examination/treatment in hospitals/clinics has been rooted in patients and citizens, and the number of prescription in 2003 is over 50%. On the process of advancing separation of dispensing and prescribing functions, understanding of meaning of “a private pharmacy” in communities, such as improving security/effectiveness of medical products through management of drug profile (drug records of patients’ previous medicine), duplicate administration, has been getting wider and the importance has been more required on the process of recent promotion of home medical care/home care.

### 【Visit to patients’ home】

Pharmacists in pharmacies do not just take prescription and just prescribe medicines but also they help improve life quality of patients who take home medical care/home care through improving effectiveness and security of medicines by visiting patients’ homes. For example, grasping management conditions of prescribed medical products and checking if those products are taken properly and if patients took all of them accordingly. If there are medical products prescribed from multiple pharmacies, confirming whether or not same kinds of medical products are taken and there is interaction by those medical products. Besides, grasping patients’ conditions whether there are symptoms concerned as side effects due to medical products, and guide to let patients learn how to take medical products are conducted. Such the supports for patients are the supports on the basis of a whole life of patients such as conditions of families living together and that of their house



and usage situation of other health medical welfare services in addition to conditions of patients' age and disease so pharmacists plays an important role as a health care provider of community medicine as well as a specialist of medicine.

Visitation by pharmacists are sometimes conducted according to instruction of doctors, and sometimes various signals, such as "notice" of pharmacists at windows of pharmacies and suggestion from visiting nurses and care managers, prompt visitation. Pharmacists who visit patients have vital roles such as focusing on very important points for patients' life, "meals, sleep, excretion and exercise", and improving their life quality with medicines, or preventing their life quality from decrease due to side effects more than requires. For examples of concrete supports, tidying patients' medicines up so that patients know easily when to take, putting labels with as big letters as patients who are partially sighted can read on medicines and sorting them out by effectiveness are some of the supports for elderly patients. Besides, changing types of medicines, recommending jelly-type medicines and changing how to take medicines depending on physical functions of patients for patients who cannot take medicines as planned are the support examples of pharmacists. Medical security and life quality of patients taking home care are improved by conducting such the supports under the cooperation with various kinds of occupation like doctors, visiting nurses and care managers.

#### **【Cancer treatment and pharmacists in pharmacies】**

Recently, patients who take cancer treatment in their home have been increasing. Cancer treatment in home have been familiarized through development of medical products and preparation of regimen (plans for each patient established on the basis of basic medical plans made depending on kinds of cancer and stage of progression or individual physical and mental condition based on such the basic medical plans. This includes administration of medicines ("supportive care") which ease side effects other than administration plan of anticancer drugs). This fact makes it possible to cure cancers without giving up daily life and help improve life quality. However, cancer treatment in their home is different from taking treatment in hospitals so medical providers cannot watch patients all the time and importance of what patients understand treatment with anticancer drugs are risen up.

For example, as for chemical therapy for cancer, it is common knowledge that preparing a certain period not to administer medicines to patients ("drug holidays") after administration for a certain period and if not following "drug holidays", administration can be too much for patients so it is necessary that patients understand meanings of administration schedule. Security/effectiveness of medical treatment is improved by that pharmacists play a role in improve of "drug compliance" by visiting patients if necessary. Besides, as for narcotics for

medical use which are used when to provide pain control and palliative care in patients' homes, since it cannot give as much effectiveness as it should be if patients stops taking medicines because of worry about dependency or if drug compliance are not well followed, it is important for patients to well understand about medicines as well as chemical therapy for cancer.

Although various side effects can come up accompanied by administration of anticancer drugs, it is required for pharmacies to observe those symptoms carefully and to take advice from a physician in charge if necessary. Besides, as for administered medical products other than anticancer drugs, instruction on dosage and administration is depending on what kind of care patients take, "supportive care" or care to deal with other factors. Flexible treatment can be available by that pharmacists in pharmacies communicate with patients with understanding patients' physical and mental conditions, detail of treatment/instruction in medical facilities and applied regimen. Since the way of "regimen" and of "terminal care" is depending on a medical facility and a doctor and profound knowledge/learning on treatment are required, growing common understanding on a routine basis through study sessions by community pharmacists in drug stores/medical facilities in addition to share of information as occasion arises is necessary.

#### **【Service at pharmacies】**

Instruction on effects/side effects of medicines and route of administration is provided depending on age-group, mental and physical condition, type of medicines and combination. Pharmacists are required, to infer with a communication in relatively short hour exactly what patients want to know, and to provide instruction on dosage and administration. What can be useful to fulfill those requirements is to utilize "Medication Notebook" and so on, and to share information and cooperate between pharmacists in medical facilities like hospitals and pharmacists in pharmacies, which is so-called "Pharmacy-Pharmacy Cooperation".

Although information on treatment of patients is available from mainly medical prescription, security can be secured by sharing information such as administered medical products which pharmacists in medical facilities recorded, explanation of prescribed medical products and contents of them through "Medication Notebook". Also, it can be more secured if it has information such as their health history, using medical products, whether or not they have experienced side effects and so on. Besides, instruction to improve patients' "Compliance" can be better by grasping a role of prescription on a process of medical treatment. Since "Medication Notebook" has possibility to improve merit of communication with pharmacists in pharmacies, we would appreciate it if all of you would more utilize it.

### 【Conclusion】

With revision of Pharmacists Act and so on in 2004, those who completed a six-year pharmacy curriculum take National Examination for Pharmacist since 2012. In 2010, students taking a “six-year curriculum” who intent to be pharmacist will start practice in community pharmacies and others. The purpose of revision to “six-year curriculum” was to train pharmacists who can face patients’ family in clinical fields as a medical provider. Accompanied by development of home medical care, it is assumed that cases of which patients receive medical treatment in their home and even die there are going to increase more and more. Therefore, it is expected for community pharmacies to perform more great work.

(Interview: Mr. Kazumasa Ooki with managing director in Tokyo Pharmaceutical Association (Shinagawa Ward, Tokyo)



### (5) Recent development in blood business and vaccines supply system

#### 1) Promotion of blood donations (Chart 2-10-4, 2-10-5)

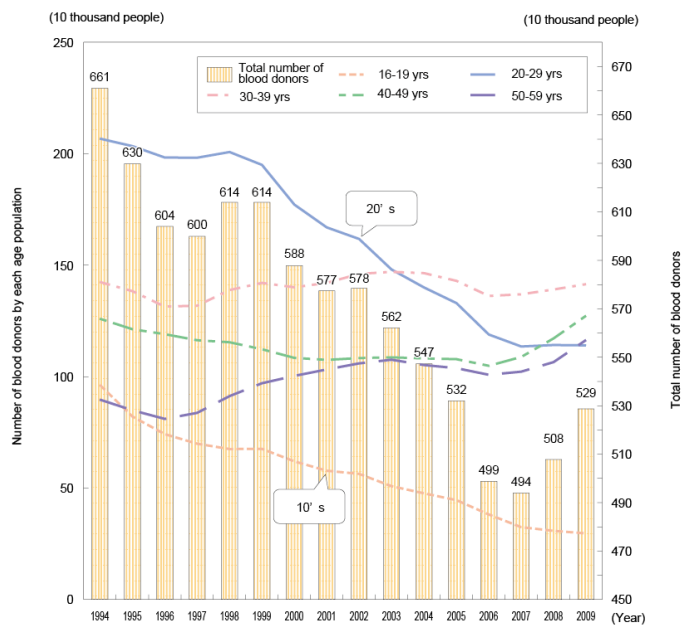
In recent years, the number of blood donors has been decreasing. Accordingly, various measures have been taken to promote blood donations through the Reform of Blood Donation Structure, which set up following goals to be achieved in about 5 years from 2005: a) increasing the number of young donors, b) securing stable group blood donations, and c) increasing multiple donation givers.

As a result, in 2009, total number of donors rose to 5.29 million (an increase of about 210,000 people or 4.1% up from the previous year), and the amount of donated blood reached 2.07 million liters (an increase of about 100,000 liters or 5.1% up over the year before). Both the number of donors and the amount of donated showed a sign of recovery.

Looking at changes in the number of blood donors by age group, however, the number of donor in their 10's and 20's has still been in a downward trend. Compared with the population decline rate over the past decade, the decline rate of blood donors in their 10's is about 2.8 times and that of in their 20's is about 1.9 times larger. Accordingly, the decline rates of blood donors for both the age groups have been reducing much faster than the population decline rate.

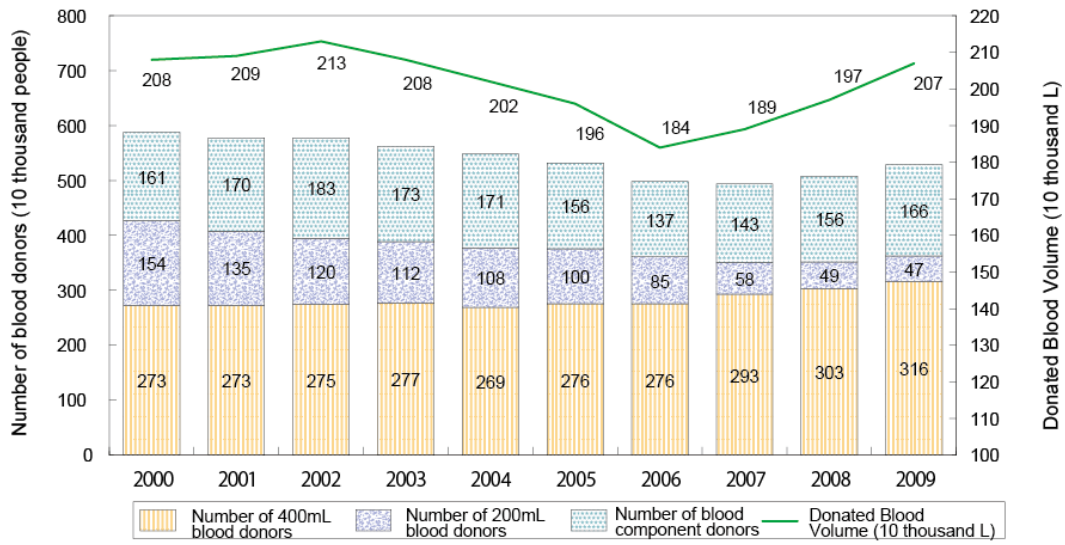
In consideration of such circumstances, the Ministry of Health, Labour and Welfare will conduct PR activities targeting young people more intensively and efficiently for example through the implementation of the campaign "Blood Donation at the Age of 20" and distribution of supplementary reader for high school students to disseminate blood donation.

Chart 2-10-4 Changes in the Number of Blood Donors



\* The number of blood donors for 2009 is a preliminary figure.  
Source: Japan Red Cross Society/Prepared by the Pharmaceutical and Food Safety Bureau, MHLW

Chart 2-10-5 Changes in the Number of Blood Donors and Donated Blood Volume



Source: Japan Red Cross Society/Prepared by the Pharmaceutical and Food Safety Bureau, MHLW



Campaign poster



Supplementary reader for dissemination

2) About the restrictions on blood donation from people who have been to Europe (Chart 2-10-6)

A vCJD (variant Creutzfeldt-Jakob disease) patient was discovered in Japan for the first time in February 2005. In order to prevent any outbreaks of vCJD through blood transfusions, tentative measure had been taken since June 2005 to temporary restrict blood donation from people who had been in the United Kingdom for one day or longer anytime between 1980 and 1996. Nevertheless, in light of the outbreak status of vCJD at home and abroad and risk assessments based on a mathematical model, the restriction measure was reviewed in December 2009 based on the restriction situation of blood donation in other countries and supply status of blood products. As a result, it was decided to restrict blood donation from those who had been in the United Kingdom for one month or longer anytime between 1980 and 1996, and the revised measure has been put into effect since January 27, 2010.

Chart 2-10-6 Restriction of Blood Donation based on the Stay History in Europe, etc.

		Country of stay	Total length of stay	Period of Stay
A	①	UK	Longer than one month (until 1996) Longer than 6 months (from 1997)	1980 ~2004
	②	Ireland, Italy, Holland, Spain, Germany, France, Belgium, Portugal, Saudi Arabia	Longer than 6 months	
	③	Switzerland	Longer than 6 months	1980~
B	①	Australia, Greece, Sweden, Denmark, Finland, Luxemburg	Longer than 5 years	1980 ~2004
	②	Iceland, Albania, Andorra, Croatia, San Marino, Slovakia, Slovenia, Serbia, Montenegro, Czech Republic, Vatican, Hungary, Bulgaria, Poland, Bosnia Herzegovina, Macedonia, Malta, Monaco, Norway, Liechtenstein, Rumania	Longer than 5 years	1980~

(Note 1) To calculate the length of stay in the countries listed in B, length of stay in the countries listed in A should be added.

### 3) Vaccines supply system

Vaccines contribute to public health as a means of preventing infectious diseases in Japan. It has become necessary, however, to establish a system for developing and providing vaccines that includes risk management to cope with the new threats to public health which have emerged in recent years, such as the new types influenza and re-emerging infectious diseases. In the meantime, internationalization has progressed as seen in vaccines produced abroad also being used in addition to those made in Japan in response to medical demands. Under such circumstances it is necessary to secure a stable supply of vaccines while maintaining their quality, in consideration of the fact that it is difficult to increase production of vaccines in response to demands in a short period of time, unlike general chemical drugs.

In light of this various issues with developing and securing the stable supply of vaccines required in Japan were published in March 2007 as the “Vision for Vaccine Industry”. The “Vision of the Vaccine Industry Promotion Committee” has also met with discussions being made on promoting the measures provided in the vision. (For vaccine-related policies that take into account the countermeasures against Novel Influenza, please refer to Section 5 in Chapter 1.)

### (6) Safety measures for chemicals

#### 1) Acquisition of Safety Information on Chemicals

Under the “Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.” (hereinafter referred to the “Chemical Substances Control Act”), the

government regulates manufacture, import, etc. of new chemicals, which have not been manufactured or imported before. The regulation is based on toxicity of a new chemical, and the toxicity is reviewed before the chemical is manufactured or imported. Regarding the safety of existing chemicals, the government conducts toxicity tests of those chemicals. In addition, information on the safety of chemicals at high production volume has been collected internationally by Organization for Economic Co-operation and Development (OECD) and also through a joint program among the private and the public sectors for collecting and releasing safety information of Japan HPV existing chemicals (named "Japan HPV Challenge Program").

In recent years, the international environment regarding the management of chemicals has been drastically changing; for instance, a new regulation on chemicals has been established in Europe. In consideration of these circumstances, the Ministry of Health, Labour revised the "Chemical Substances Control Act" in cooperation with the Ministry of Economy, Trade and Industry and the Ministry of Environment, and the revised Act was promulgated in May 2009. The revised law stipulates that manufacturers/importers which manufacture/import more than a certain amount of chemicals including the existing ones are obliged to report the amount, etc. every year in order to implement the risk assessment steadily and also to promote rigid management of chemicals in Japan. Concerning chemicals which will be regulated under the international treaty, the regulation will be revised to approve their exceptional uses under rigid control, which are allowed by the international treaty, for the purpose of global harmonization of chemical regulations. Part of the revised law was enforced in April 2010, and the entire Act is planned to be put into effect in April 2011.

In addition, the government ordinances were amended in order to designate 12 chemicals, which were added to the subject to control at the international convention concerning management of chemicals (Stockholm Convention) which was held in May 2009, as class I specified chemical substances (substances whose production and import are in effect prohibited with the exceptions of the irreplaceable substances for specific usages) based on the Chemical Substances Control Act. The revised ordinances were promulgated in October 2009 and have been enforced since April 2010.

## 2) Safety Measures for Household Products

In order to prevent health damages caused by chemical substances used in household products (excluding pharmaceuticals and medical devices, and hereinafter the same shall apply), regulatory standards have been set for textile products, cleaning agents, and timber for gardening in accordance with the "Act for the Control of Household



Products Containing Harmful Substances” (as of the end of FY2009, standards had been set for 20 substances). In addition, guidance and enlightenment activities have been carried out through making public of serious accidents associated with the use of household products which are assumed to be caused by chemicals and utilizing health damage report system concerning household products.

### 3) Safety measures for poisonous and deleterious substances

Pursuant to the “Poisonous and Deleterious Substances Control Act”, chemicals with acute toxic reactions have been designated as the poisonous or deleterious substances in order to regulate handlers of these substances. As of the end of FY2009, 109 items had been designated as poisonous substances and 370 items as deleterious substances in accordance with the Act.

## 4 Food safety measures

### (1) Government roles and responsibilities for food safety

Food choice and eating habits in Japan has drastically changed over the years due to the technological advances in food manufacturing and the increasing quantities of imported foods. Accordingly, consumers’ concerns about food safety have been rising.

Following the high-profile cases of food issues such as BSE, pesticide residues in imported vegetables and poisoned Chinese frozen ‘gyoza’ dumplings in 2008, the consumer demand for food safety has been growing.

In the wake of establishment of the Food Safety Basic Act and the revision of the Food Sanitation Act (enacted in 2003), Japan has introduced a risk analysis approach to food safety. Risk assessment organization is established to undertake risk assessment of the health effects of food independently from the risk management organization. Meanwhile, risk management organization is focusing on formulating specifications and standards as well as conducting surveillance and inspection. Under this new established framework, the Ministry of Health, Labour and Welfare is making the effort to enforce food safety in cooperation with local governments and related ministries and agencies, and with public support.

With the foundation of the Consumer Affairs Agency in 2009, responsibilities for food labeling based on the Food Sanitation Act and nutrition labeling standards in accordance with the Health Promotion Act has been transferred to this agency.

### (2) Current situation with food safety measures

Some of the key food safety measures are described below.

1) Establishment and revision of specifications and standards

① Confirmation of the usage/distribution and the safety on existing food additives

Since its enactment in 1947, the Food Sanitation Act had permitted the use and distribution of chemically synthesized food additives only when these additives were designated as safe by the Minister of Health and Welfare (at the time). Subsequently, at the revision of the law in 1995, the application of designation system was expanded to so-called natural additives (except for natural flavoring agents and substances that are generally provided for eating or drinking and also used as food additives) to respond to the possibility that substances derived from plants and animals without any history of human consumption as food would be used as food additives.

In response to the expansion of application, 489 items of “natural additives” that were already marketed at the time of 1995 were permitted to be used as “existing food additives” because of a long history of use as food additives without any negative health effect reported. On the other hand, the MHLW has worked to confirm their safety systematically. In addition, the MHLW has withdrawn existing food additives from the List of Existing Food Additives (Ministry of Health and Welfare Announcement No. 120 of 1996) if they are determined to be no longer marketed in Japan. To date, one item with safety problem and 70 items not in use have been delisted. As of January 2010, 418 existing food additives were permitted for use or distribution. In preparation of a third round of withdrawal, the MHLW has started discussion for existing food additives whose use situation is not clear.

② Discussion on the designation of additives which are globally evaluated as safe

Discussion on the designation of additives which are globally evaluated as safe.

Specifically, the safety and necessity of following food additives are being discussed in principle for each item toward designation even without requests from companies: additives a) whose safety has been confirmed within a certain definite range by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and b) that are widely used in the United States and EU countries and are globally recognized as necessary.

The MHLW has prioritized food additives that meet the above selection criteria and collected necessary information on them. By July 2010, the MHLW requested risk assessment for 36 food additives and 40 flavoring agents to the Food Safety Commission of Japan (FSCJ) in the Cabinet Office. Among them, 28 food additives and 28 flavoring agents were designated after going through assessment by the FSCJ and discussions at the Pharmaceutical Affairs and Food Sanitation Council.

### ③ Revision of the official compilation of food additive specifications and standards

The Minister of Health, Labour and Welfare prepares an official compilation of food additive specifications and standards, *Japan's Specifications and Standards for Food Additives*, to clarify the regulations on food additives and to promote the appropriate usage of food additives. The publication is updated approximately every five years to provide new information on specifications and standards and to accommodate the progress of manufacturing technology, quality control and testing methodology. The latest edition (the 8th edition) was published in 2007.

On revision of the official compilation, a study group consisting of people with expertise makes discussions on reviewing the general testing methods and compositional specifications, establishing specifications and standards for existing additives, and improving the general descriptions of specifications.

The MHLW will set up a new study group to prepare the 9th edition soon.

### ④ Positive list system for agricultural chemical residues in foods

On May 29, 2006, the positive list system took effect to control agricultural chemicals (in this publication, the term "agricultural chemical" include pesticides, food additives and veterinary drugs) remaining in foods. This system, in principle, aims to prohibit the distribution of foods that contain agricultural chemicals at levels exceeding a certain limit (0.01 ppm) specified under the act unless specific residue limits are established for these chemical-food combinations.

As of July 2010, the maximum residue limits (MRLs) were established for 819 agricultural chemicals, including the MRLs set after the enforcement of the system.

Since the fiscal year 2006, the MHLW has annually formulated plans for review and asked the FSCJ to conduct risk assessment for agricultural chemicals for which MRLs were newly established at the introduction of the system. The MHLW is working to review the current MRLs based on the assessment of the FSCJ, hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council.

Continuous efforts will be made to disseminate the system and to develop analytical methods in order to ensure the appropriate and smooth implementation of the system.

### ⑤ Measures for controlling contaminants

Regarding contaminants in foods, the Pharmaceutical Affairs and Food Sanitation Council has set out a basic concept for the establishment of standards and specifications. Concretely, the concept is: a) for foods for which international standards are established, to adopt the international standards if these standards are determined to be appropriate; b) to

request relevant stakeholders to promote technological development for the measures to reduce contaminants and, when necessary, to set the standard or guideline limits based on the principle of “As low as reasonably achievable” in cooperation with these stakeholders if it is difficult to adopt international standards in light of the situation of food production in Japan; and c) to carry out review as appropriate in the future if the MHLW determines that it is not immediately necessary to establish standards in light of the contaminant occurrence in foods distributed in Japan and Japanese food intake.

Based on concept, measures have been taken to review the standards and specifications for cadmium in rice, to promote the measures to reduce cadmium contamination, and publicize precautions for pregnant women about the intake of mercury-containing seafood.

#### **⑥ Measures for apparatus, containers / packaging, and toys**

The MHLW also establishes specifications and standards for apparatus and containers/packaging in order to prevent health hazards caused by drinking or eating. With regard to phthalate and bisphenol A used for apparatus and containers, the MHLW is going to take appropriate measures based on the results of assessment, which is being carried out by the FSCJ .

In addition, the Food Sanitation Act establishes specifications and standards for toys designated by the Minister of Health, Labour and Welfare as those that may harm the health of young children through contact therewith (hereinafter referred to as “designated toys”). Since 2002 Japan has restricted the use of two types of phthalates in polyvinyl chloride used as raw material of the designated toys. The MHLW is considering reviewing current specifications and standards for designated toys, taking into account the global consistency.

### 2) Establishment of monitoring and inspection system

#### **① Plan-based monitoring and guidance**

For the purpose of securing food safety, it is critical to implement monitoring and guidance in cooperation between the Ministry of Health, Labour and Welfare and related administrative organizations such as prefectural governments. In order to carry out their intensive, efficient, and effective implementation, “The Guideline for Implementation of the Monitoring and Guidance regarding Food Sanitation” was established. In addition, the Ministry of Health, Labour and Welfare is to formulate, announce and implement a supervision and instruction plan every year for imported food, while prefectural governments will be in charge of making domestically-traded food plans with consideration given to the actualities of their respective regions.

## ② Securing Safety of Imported Food

(Situation with imported food)

The reported number of cases and volume of imported food have been increasing every year, reflecting the decline in the Self-Sufficiency Ratio of Food and diversity of consumer needs.

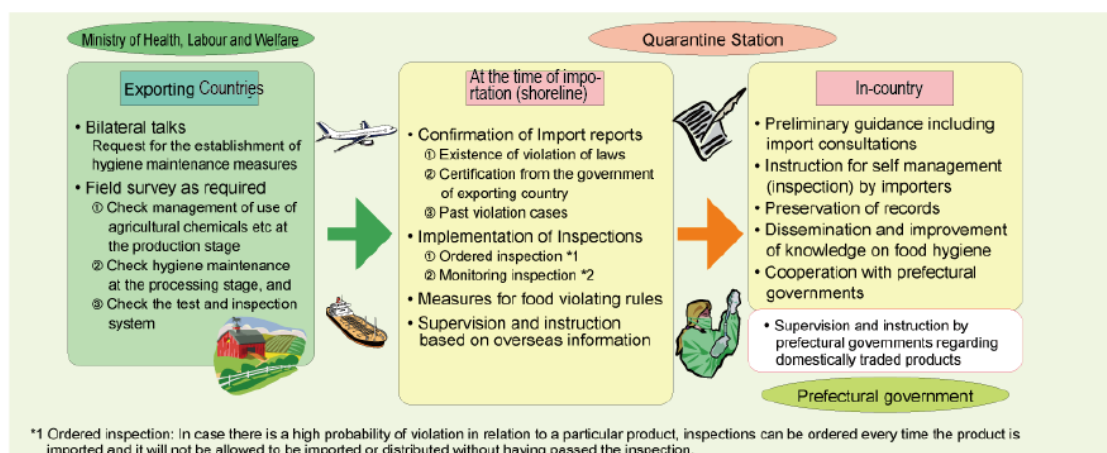
(Efforts for securing safety of imported food)

To secure the safety of imported food, the Ministry of Health, Labour and Welfare formulates a “Monitoring and Guidance Plan for Imported Foods” every year in implementing intensive, effective, and efficient supervision and inspections. In this plan governmental organizations take measures at three stages: in exporting countries, at the time of importation (shoreline), and in-country (Chart 2-10-7). If any violations are repeatedly detected in the system, bilateral talks or on-site inspections as required are conducted in consideration of prohibiting the export of the relevant food stuffs, while requesting the relevant exporting countries to take measures at the production/manufacturing stage.



Sampling inspection for imported meat

Chart 2-10-7 Measures to Secure Safety of Imported Food

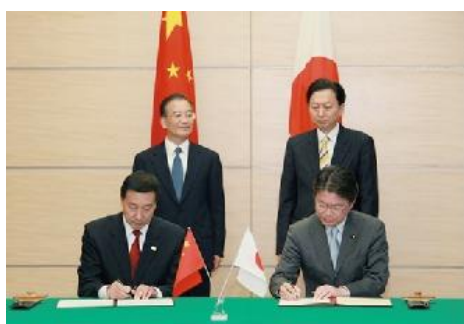


In addition, the number of inspectors at quarantine stations was increased significantly, in order to upgrade the inspection devices for pesticide residue by revised budget of FY 2009 and the inspection buildings at the Center for Inspection of Imported Food and Infectious Diseases (in Yokohama and Kobe) were expanded. Since FY 2009, information collection and evaluations related to sanitation maintenance measures taken by exporting countries have been promoted in addition to conventional bilateral cooperation and on-site inspections conducted when a problem occurs. In November 2009, at the Tripartite Health Ministers Meeting (THMM) between China, Japan and Korea, a memorandum of understanding was signed to set up a consultation mechanism to strengthen tripartite exchanges and cooperation in the area of food safety (Chart 1-3-4 in Section 3, Chapter 1.).

In addition, the Japan's Minister of Health, Labour and Welfare and the China's Minister of General Administration for Quality Supervision Inspection and Quarantine signed a memorandum concerning the "Japan-China Food Safety Promotion Initiative" when Chinese Premier Wen Jiabao visited Japan in May 2010. The Initiative was proposed by Prime Minister (at that time) Yukio Hatoyama at the Japan-China summit in October 2009 to hold talks on a periodical basis by the ministers in charge aiming at promoting food safety between Japan and China. Furthermore, at the "First Minister-level Talks for the Japan-China Food Safety Promotion Initiative", an agreement was reached based on the memorandum on the action plan of this year concerning specific mutual interests to be discussed at the ministerial level, including the residual pesticides in agricultural products from China. In accordance with this action plan, both ministers agreed to promote communities and cooperation in safety of foods, which are traded between two countries.

According to the "Statistics of Imported Food Monitoring" (2008) prepared by the

Department of Food Safety, Pharmaceuticals and Food bureau of the Ministry of Health, Labour and Welfare, inspections at the time of import were conducted for 190,000 cases, and 11.0% of the total reported number of import cases of 1.76 million. Violations were detected in 1,150 cases (0.1% of the reported number) of the inspected cases. Standards on the ingredients of frozen foods, standards of additives use, and standards of pesticide residues in vegetables are violated often. The food involved in violations was disposed of or returned.



Signing ceremony for the Memorandum on Japan-China Food Safety Promotion Initiative  
(Picture credited by Cabinet Public Relations Office)

### ③ Measures against food poisoning

As a result of the development of a distribution system in recent years there is a growing concern that food poisoning outbreaks could spread throughout wide areas. In September 2009, at the restaurant chain, the diffuse outbreak of *Escherichia coli* O157 was caused in insufficient heat treatment of processed meat with biding treatment, etc.

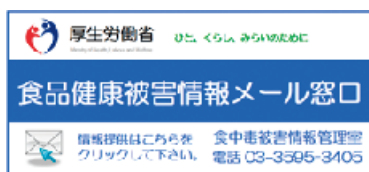
In 2009, prefectural governments reported 1,048 cases of food poisoning, with the number of patients being 20,249 and without anyone having died. The number of case has been declining since 1998, when it reached a peak, and the number of patients in 2009 decreased by 4,000 from that in 2008 (24,303 patients).

Although the major cause of food poisoning has traditionally been bacteria such as *Campylobacter* and *Salmonella*, increases in viruses such as the Norovirus have also been reported in recent years. Food poisoning cases caused by the Norovirus, in particular, resulted in more than 20,000 patients being reported in 2006, a large increase from 2005 and earlier in which the number of patients was around 10,000 annually. As there are many genotype of Norovirus, it is impossible to increase their number for use in cultured cells or in experimental animals, and it is often difficult to clear up the cause or identify the route of infection because patients have been infected through contact with other people in many

cases, and hence problems remain unsolved for taking measures against it.

The Ministry of Health, Labour and Welfare is promoting basic research that will contribute to measures against bacterial food poisoning and viral food poisoning. In addition to Q&A on *Campylobacter* and Norovirus\*14, illustrations and video contents about 6 things to do at home for food poisoning prevention were created and posted on the websites of the Ministry of Health, Labour and Welfare in order to promote correct knowledge on food poisoning and to deepen understanding of preventive measures among the nation.

In consideration of chemical food cases involving Chinese frozen 'gyoza' dumpling which occurred in January 2008, the Management Office of Foodborne Disease Surveillance was established in April 2009 within the Inspection and Safety Division, Food Safety Department, Pharmaceuticals and Food bureau of the Ministry of Health, Labour and Welfare in order to aggregate/centralize information on food poisoning from prefectures. In addition, an Information Corner for Health Damage Caused by Foods was launched on the website of the Ministry of Health, Labour and Welfare for the purpose of extensively collecting and identifying information on health damages caused by eating/drinking.



<http://www.mhlw.go.jp/topics/bukyoku/iyaku/syoku-anzen/mail-madoguti/index.html>

#### ④ BSE control measures

(Measures against outbreak of BSE in Japan \*15)

In response to the increase in European nations where BSE (Bovine Spongiform Encephalopathy) has broken out, the Ministry of Agriculture, Forestry and Fisheries and the Ministry of Health, Labour and Welfare have been promoting the establishment of an inspection system for BSE. The first BSE case in Japan was detected in September 2001. And in response, elimination and incineration of specified parts (heads excluding tongues and cheeks, the spinal cord, and the distal ileum) were made compulsory on October 18, 2001, covering all cattle processed and used for food. At the same time BSE inspections were introduced at all slaughterhouses in Japan. And hence a system to stop the distribution of beef etc from BSE-infected cattle has been established.

On September 9, 2004, assessments and inspections related to domestic measures against BSE were summarized by the Food Safety Commission. The Ministry of Health,



Labour and Welfare, together with the Ministry of Agriculture, Forestry and Fisheries, questioned the Food Safety Commission on revision of domestic BSE measures (so-called risk management measures) on October 15, 2004 and the commission submitted a report on May 6, 2005. In response to this report, the system was amended so that only cattle 21 months old or older will have to undergo BSE inspections.

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\*14 Q&A on Campylobacter food poisoning

<http://www.mhlw.go.jp/qa/syokuhin/campylo/index.html>

Q&A on Norovirus

<http://www.mhlw.go.jp/topics/syokuchu/kanren/yobou/040204-1.html>

6 things to do at home for food poisoning prevention

<http://www.mhlw.go.jp/topics/syokuchu/dl/point.pdf>

\*15 Division of Roles between Related Offices and Ministries with BSE Measures

The Ministry of Health, Labour and Welfare promotes measures to secure the safety of meat in compliance with the Act on Slaughterhouses and Food Sanitation Act. The Ministry of Agriculture, Forestry and Fisheries promotes measures to prevent infectious livestock diseases and secure the safety of livestock feed at the production stage in compliance with the Act on Domestic Animal Infectious Diseases Control and the Act on Securing the Safety of Livestock Feed and Improving Quality. These two ministries are in charge of managing the risk (the probability of emergence and degree of adverse impacts harmful substances in foods could cause on health as a result of being eaten).

On the other hand, a Food Safety commission within the Cabinet Office, which was organized in 2003, evaluates risks (evaluations on the impact of food on health) independently of other related administrative organizations managing risk. These related office and ministries closely cooperate in taking measures.

As of December 2009, and as a result of BSE inspections conducted at slaughterhouses, 21 BSE infected cattle had been identified. In Japan, 36 cattle have been confirmed as infected with BSE, including the 21 cattle mentioned above, the first cow being discovered in 2001, and 14 dead cattle. As a measure for BSE, cease of pisting\*16 had been promoted because it could contaminate dressed carcass through blood circulation and enhance the risk of BSE to meat, while paying attention to the balance of securing safety for both meat and workers. In consideration that pisting was ceased at all slaughterhouses in April 2009, the Ordinance for Enforcement of the Slaughterhouse Act was revised to prohibit pisting

also in the system.

(Measures against outbreak of BSE in the United States etc.)

Beef and beef products imported from countries where BSE has broken out, including EU nations, are not allowed to be imported until having had confirmed an equivalent safety level to Japan, in making it absolutely certain that the safety of these products traded in Japan is secure.

In response to the BSE outbreak in Canada in May 2003 and in the United States in December 2003, importation of beef produced in Canada and the United States was prohibited. Since then, however, discussions have been held with the United States etc. on resuming the beef trade. Taking into consideration the results of evaluations on the impact of food on health by the Food Safety Commission within the Cabinet Office, importation of beef produced in the United States and Canada was then resumed on December 12, 2005. However, veal including spinal columns did arrive from the United States on January 20, 2006, and hence importation of all beef produced in the United States was then ceased.

Subsequently, taking into consideration a report from the US government that clarified the cause and recurrence preventive measures against it and the results of exchanging opinions with consumers, field surveys of qualified facilities exporting beef to Japan were conducted by Japan, and the importation of US-produced beef was then resumed on July 27, 2006.

Japan is verifying the compliance status of the US import program to Japan through conducting regular field surveys that include accompanied unannounced inspections in the United States and import inspections at quarantine stations. Efforts will continue to be made to ensure that the import program to Japan is being observed by the United States and that the appropriate information is being provided to consumers.

In addition, a request was made by the United States to review the import conditions in following standards laid down by the World Organisation for Animal Health (OIE) in June 2007. In response to this, technical discussions were held between executives in Japan and the United States in June and August 2007. A report on the discussions is being jointly compiled by these two countries. It will be handled utilizing scientific knowledge in cooperation with the Ministry of Agriculture, Forestry and Fisheries with the provision that the safety of food and consumers' trust is the major premise.

#### **⑤ Measures for drug-poisoning cases involving Chinese frozen 'gyoza' dumplings**

Ten cases of suspected organophosphorus poisoning from people eating Chinese frozen 'gyoza' dumplings imported from China in Chiba and Hyogo prefectures have occurred

since December 2007. Later, as a result of inspections by related organizations, it was reported that methamidophos, an organophosphate insecticide, had been detected, in amounts exceeding standard values from packaging of the products and Chinese-style dumplings, in vomit.

In response to this, the Ministry of Health, Labour and Welfare made the public announcement that people should avoid eating the product and ordered an immediate recall after receiving the information from the viewpoint of preventing any further damages. In addition, the government compiled "Preventive Measures against Recurrence of Drug Poisoning Cases through Food" (related ministers' agreement on drug poisoning cases through food) on February 22, 2008.

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\*16 Pishing refers to the method to destroy brain and the spinal cord by using wire or other similar instruments.

In accordance with this, Article 73 of the Ordinance for Enforcement of the Food Sanitation Act was revised in April 2008 to expand the scope of food poisoning cases that prefectural governors are required to report to the Minister of Health, Labour and Welfare immediately as part of improving the system of collecting/centralizing information. In addition, the "Guidelines for Managerial/Operating Standards to be implemented by Business Operators of Foods" for establishing a Prefectural Ordinance was revised so that rules for business operators of foods to promptly make reports to health centers were established. Furthermore, the scope of the processed foods which are subject to pesticide residue inspections at quarantine stations has been expanded, starting from the one those inspections have become technologically available. In addition, the "Guideline on Hygiene Control of import Processed Foods" was compiled in June 2008 with the aim of increasing hygiene maintenance in exporting countries.

Further efforts will be made to strengthen the measures to secure imported food safety such as through increasing the number of foods-sanitation inspectors at quarantine stations and upgrading the inspection devices.

## ⑥ Securing safety of health foods

Because of people's growing interest in their health, various health foods are now being sold as health food. Some of them never before generally served for human consumption and others are in a peculiar form. In July 2008, the 'Study Group for Securing Safety of

“Health Food” compiled a report aiming at supplying safe and secure products to consumers.

The report stated that “concrete measures to secure safety of “health foods” at production stage” need to be enhanced, including Raw Materials Safety Self-Inspection Guidelines and Proper Management of Production Process Guidelines. In addition, it is appropriate to pay attention to securing safety of raw materials and securing safety as well as effectiveness through management of production process in order that consumers can understand those measures. At the same time, the report suggested that “enhancement of a system to collect and process information on health damage” and “dissemination and enlightenment for consumers” need to be promoted. In consideration of this, it was decided that an independent organization, which is voluntarily managed by an organization of business operators, authorizes each food for its securing of raw materials safety, and securing of safety of management of production process following the guidelines established by the Ministry of Health, Labour and Welfare. Guidance will be continuously provided to business operators of foods in order to enhance a system to collect and process information on health damage.

### (3) Providing accurate and clear information

#### 1) Measures for risk communication

Provision for risk communication (exchanging information and opinions on risk) was included in the Food Safety Basic Act of 2003 as an important factor in risk analysis. More concrete provisions for listening to citizens and residents (so-called risk communication provision) were also included in the Food Sanitation Act that provides measures for securing individual food safety (risk management measures).

The Ministry of Health, Labour and Welfare is taking measures on risk communication in cooperation with the Food Safety commission within the Cabinet Office, the Ministry of Agriculture, Forestry and Fisheries, and local governments.

Based on the results of discussions made at the “Study Group on Risk Communication on Food Safety”, which was compiled in March 2005, the operating plans for programs have been formulated at the beginning of each fiscal year, and opinion exchange meetings have been held in a well-planned manner with the themes ranging from the measures to secure imported foods safety, pesticide residues, BSE, health foods, food additives to food poisoning since FY 2005.

In addition, efforts are being made including distribution of various pamphlets, improving the content of websites, and promoting cooperation between related organizations and consumer organizations.

In partnership with the Consumer Affairs Agency, which was founded in 2009, opinion exchange meetings with related entities, including consumers, will be continued to be actively held. In addition, improvements will be repeatedly made to make the system better.



Risk Communication concerning Foods  
(Opinion exchange meeting)

## 2) Information collection and research for securing food safety

As dietary habits have diversified, the risks to health caused by eating/drinking are also becoming more diverse. Hence it is necessary to collect variety of information both domestically and from abroad, have related institutions share it, and then implement risk management measures based on science in securing food safety.

With the system used to collect information, information on food safety both domestically and from abroad is collected, analyzed, and distributed to related entities by Division of Safety Information on Drug, Food and Chemicals of the National Institute of Health Sciences. The Drug, Food and Chemicals of the National Institute of Health sciences Research collects, analyzes and distributed information to national and local government organization. Research on securing food safety is also being conducted at national research institutions. In addition, a broad range of research is being conducted through Health and Labour Science Research Grants that includes investigation/research on formulating specifications and standards, research/development on establishing official inspection methods, and research on safety.

## (4) International normative activities for food safety in Codex

The Codex Alimentarius Commission (Codex) is an international intergovernmental organization jointly established by Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO) in 1963. Codex aims to protect the health of the consumers and to ensure fair practices in the food trade. Codex standards and related

texts are referred to as international standards in the SPS Agreement, which encourages harmonizing national regulations with the international standards under the multilateral trade agreement of the World Trade Organization (WTO).

Codex consists of Commission, Executive, General Subject Committees(10), Commodity Committees(11), *ad hoc* Intergovernmental Task Force (2) and Regional Coordinating Committees(6).

The Codex standards for foods have a great impact on risk management in Japan. The Ministry of Health, Labour and Welfare, in collaboration with the Ministry of Agriculture, Forestry and Fisheries and other administrative organs, and research institutes, actively participates in Codex work.



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## 5 Promotion of preventive measures against suicide \*17

As the number of people who have committed suicide remains high at around 30,000 annually since 1998, measures against suicide have become an urgent issue. The Japan's suicide rate (the number of people died by committing suicide among 100,000 persons) is the highest among the seven developed countries; and among them, Japan is the only nation where suicide is the leading cause of death for the young people age 15-34. Accordingly, suicide has become an issue that should be addressed urgently.

Suicide is the result of diverse and a combination of factors, but mental illnesses such as depression are the predominant reason. According to the statistics released by the National Police Agency, people who died by suicide due to depression account for about one third among the suicides whose factors/motivations have been identified. Therefore, it is important to promote measures against suicide focusing on proper support for people with depression.

Considering this, and in response to the Basic Act on Suicide Prevention approved in 2006, the "General Policies of Comprehensive Measures against Suicide" (hereinafter

referred to as the “General Policies”) was formulated in June 2007 as guidelines for measures to be promoted by the government. The General Policies provided for measures against suicide to be strongly promoted in close cooperation between the government, local governments, medical institutions, and public organizations, and the goal set of reducing the death rates from suicide by 20% or more from that of 2005 by 2016. The General Policies were revised in October 2008 to strengthen measures for people with high risk of suicide except patients suffered from depression.

The Ministry of Health, Labour and Welfare has been making efforts, including providing information at the Suicide Prevention Comprehensive Measure Center established in the National Institute of Mental Health of the National Center of Neurology and Psychiatry (established in October 2006), promoting effective measures against suicide and supporting measures of business operators in communities, improving the consultation system and human resource development for preventing suicide, and promoting/disseminating/enlightening the results of comprehensive investigations and research of suicide issues.

Regarding caring for families of people who have attempted/committed suicide, which is one of the major pillars for suicide control, the guidelines for counseling and support were formulated in FY 2008. Based on the guidelines, training programs have been carried out with the aim of enhancing the qualification of care workers. Efforts have been also made to improve the medical system, for example by offering training to primary-care physician so that they can detect the people suffer from depression at an early stage and provide them with proper treatment. (For mental health measures for workers, please refer to Section 7-3-(3)-2.)

In January 2010, the “Anti-Suicide and Depression Project Team” (hereinafter referred to as the “Project Team”) was established under the Ministry of Health, Labour and Welfare to understand the actual situation of suicide and to have discussions on the more efficient suicide measures, and the report was compiled in May 2010. Aiming at realizing a warm society where everyone can live without anxiety, the Ministry of Health, Labour and Welfare will take anti-suicide measures, based on the report, focusing on: a) intensive implementation of enlightenment activities; b) enhancement of function as a gatekeeper and establishment of regional cooperation system; c) improvement of mental health measures at workplace and support for return to work; d) improvement of outreach (visit support) ; and e) promotion of mental health and medical reform.

Furthermore, in response to the indications given by the Health and Labour Science Research and mass media concerning interrelationship between excessive dose of psychotropic drugs and suicide, the Project Team has carried out discussions since July

2010 on prescription of psychotropic drugs.

The number of people who committed suicide, which is released by the National Police Agency, has been decreasing from the same month of the previous year for ten consecutive months since September 2009. The Ministry of Health, Labour and Welfare will continuously promote suicide control measures in cooperation with the Cabinet Office to “protect life” of as many people as possible.

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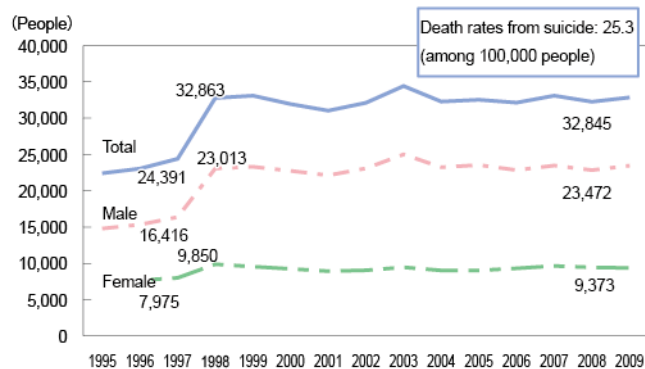
\*17 Preventive measures against suicide

<http://www.mhlw.go.jp/bunya/shougaihoken/jisatsu/index.html>

The report compiled by the “Anti-Suicide and Depression Project Team”

Chart 2-10-8 Current Situation of Suicide in Japan

• The number of people committed suicide increased rapidly in 1998 and has maintained the high level of about 30,000 people per year since then.  
• Suicide is the result of diverse and a combination of factors, but mental illnesses, particularly depression, schizophrenia and dependence, are considered to be the predominant reasons.

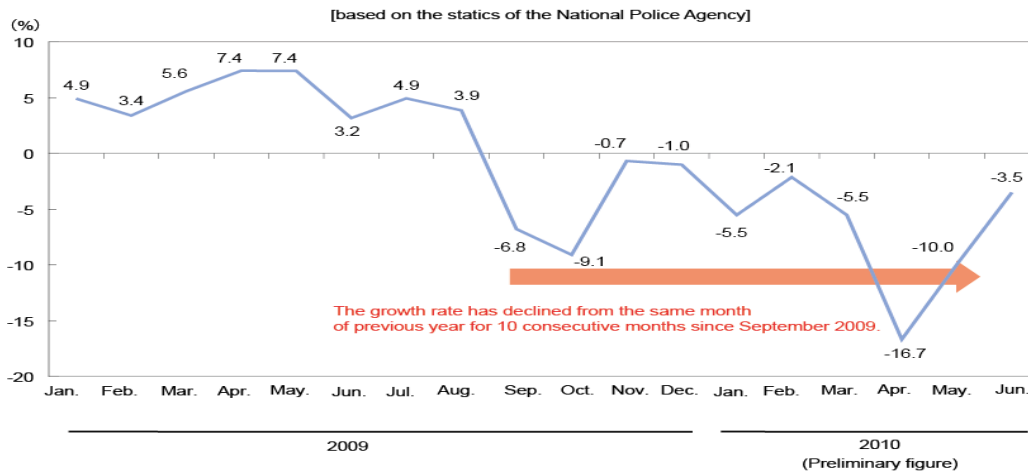


**Numerical targets for the Measures against Suicide**  
【General Policies of Comprehensive Measures against Suicide (formulated on June 8, 2007)】  
Reduction in the death rates from suicide by 20% or more by 2016 (from 2005)  
\* Death rate from suicide in 2005: 25.5 (among 100,000 people, the statistics of the National Police Agency)

Source: “Overview of Suicide” National Police Agency



Chart 2-10-9 Monthly Growth Rate of Suicide (YoY)



## 6 Health risk management system

The Ministry of Health, Labour and Welfare has been promoting health risk management through establishing the required systems in accordance with the “Basic Guidelines for the Management of Health Risk” that was revised in January 2001 following restructuring of the ministries and other governmental agencies to ensure prompt and appropriate responses to health risks that threaten people’s health and lives. (See Section 9-1, Chapter 1)

## 7 Stable supply of safe and high quality water

As water is essential to people’s lives, it is necessary to ensure a safe stable supply of it. The Ministry of Health, Labour and Welfare formulated the “Waterworks Vision” to show a road map toward ideal waterworks in the mid-21st century using five key words.

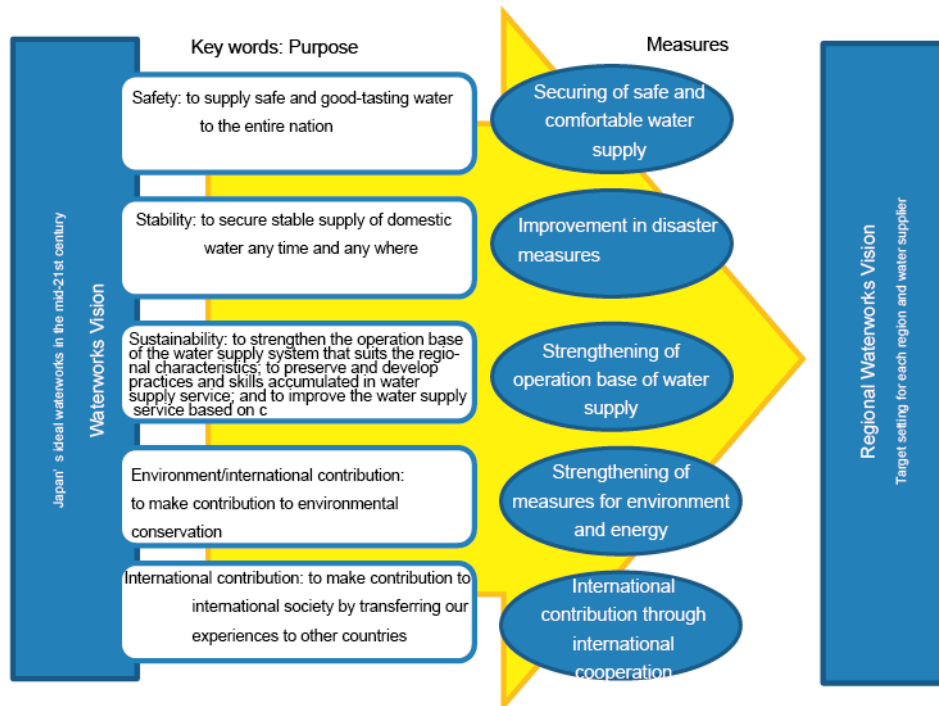
### (1) Safety: to supply safe and good-tasting water

In order to secure safe, high quality water that conforms to water quality standards, it is important to fully implement water quality management from the source of the water through to taps. Water quality standards had been set for 51 items as of the end of FY 2009 and are reviewed repeatedly taking into consideration the latest scientific knowledge through collecting knowledge and conducting research as required.

With regard to the measures for individual issues, through management of water tanks in buildings and apartment houses of concern for contamination and switching to direct water supply system have been promoted. In addition, as measures against Cryptosporidium,

which is an infectious protozoan that is resistant to chlorine, new treatment with ultraviolet light was approved for water treatment and a “Guidelines for Cryptosporidium Treatment in Waterworks” were formulated in March 2007 to thoroughly take measures.

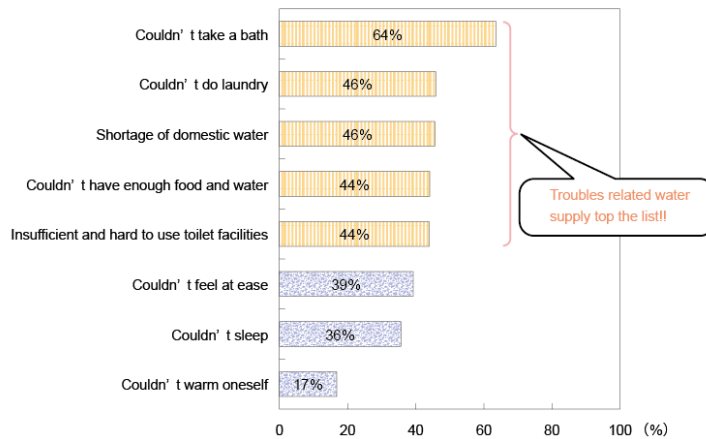
Chart 2-10-10 Japan’s Waterworks Vision and Regional Waterworks Vision



(2) Stability: to secure stable supply of domestic water any time and any where

In order to secure stable water supply for people, even in times of natural disasters including earthquakes or in emergency cases such as water quality accidents, water suppliers are expected to secure the safety of core water supply facilities and have a prompt recovery system ready (Figure 2-10-11). Considering that water supply facilities were also suffered great damage in the earthquake disasters that have frequently occurred in recent years, an Ordinance of the Ministry on technical standards for water supply facilities was revised to clarify the earthquake-resistant functions that water supply facilities should provide in promoting measures against earthquakes (and enforced on October 1, 2008). In addition, efforts have been continuously made to promote measures to systematically improve the earthquake-resistance of existing water supply facilities.

Chart 2-10-11 Troubles One Week after the Earthquake (Survey for the Victims of the Great Hanshin and Awaji Earthquake)



Source: Survey on Response by Residents and Transmitting Disaster Information at the Great Hanshin and Awaji Earthquake (partly revised)

### (3) Sustainability: to strengthen the operation base of the water supply system

With revenue reduction of the water rate caused by decreasing population and replacement demand increase for dilapidated facilities, water suppliers, especially small-scale suppliers with weak operation base, are expected to face a severe operation situation in the future. The Ministry of Health, Labour and Welfare created the “Guidelines for Asset Management in Water Works” in April 2009 to offer support to draw up plans for replacement demands taking into account future replacement demand and financial balance, and then, sent the guidelines together with support software program to water suppliers. Aiming at upgrading the dilapidated facilities in a well-planned manner and smoothly operating the water works while preventing the water rate hike, the Ministry of Health, Labour and Welfare will continue to actively offer technical assistance, along with amalgamated water works and promotion of use of the private sector

### (4) Environment/international contribution: to make contribution to environmental conservation and international society

Since water works consumes about 0.9% of all electricity in Japan, it is expected to make contribution to environmental conservation through efficient energy use, reduction of wastes such as sludge from purifying plants and effective water use. In addition, taking advantage of our experiences in Japan, efforts will be made to contribute to the improvement in water supply environments in other countries through international contribution by technology transfer and other international cooperation.



Example of dilapidated facility

## 8 Environmental health measures

### (1) Promotion of environmental health measures

“Environmental health industries” are industries that are closely related to people’s lives and include barber shops, beauty salons, laundries, hotels and inns, public bath houses, places of entertainment, restaurants, cafes, butchers, and ice and snow shops. To facilitate the development of these industries and maintain/improve their health level, and thereby contributing to improved/enhanced public health and stabilization of people’s life, various measures are being taken including consideration in budget, financing, and taxation.

For the purpose of promoting energy conservation in the environmental health industries, the FY 2010 budget was allocated for implementation of surveys to collect basic data concerning implementation status of food recycling and volume of food wastes. In addition, the “Guidelines for Food Recycling Promotion”, which was established in March 2004, will be reviewed to promote its dissemination.

Furthermore, the Japan Finance Corporation (JFC) makes loans to environmental health business operators in order to maintain/improve the health level of environmental health industries. Since April 2010, the interest cut measures for the Loans for Business Promotion has extended its period. Financial support will be continuously offered for people who are running environmental health businesses.

### (2) Promotion of health measures in buildings

Buildings of a certain scale used as places of entertainment, department stores, shops, offices, and schools (specific buildings) are obligated to be maintained/managed in accordance with the building sanitation management standards in securing health in buildings.

As buildings are becoming larger in scale and used in more complicated ways, advanced

level maintenance/management of buildings is being required. In addition, there are issues such as the so-called "Sick House Syndrome", which involves various health problems being caused by chemical substances in buildings. And hence a standard amount of formaldehyde in the air inside rooms was added in building sanitation management standards in 2003 to prevent such health damage from occurring.