

Section 7. Promotion of Measures against Infectious Diseases

1. Measures against Intractable Diseases

Measures against intractable diseases have centered on the five principles of “promoting investigations and research”, “providing medical care facilities”, “reducing the co-payment for medical costs”, “improving and coordinating community-based health care, medical care, and welfare services”, and “promoting welfare measures aimed at improving people’s quality of life (QOL)”. Based on these principles provision for health, medical and welfare services for patients with serious conditions have been promoted.

With regard to the specific disease research program the decision was made in June 2008 including to add 7 new diseases to the subject diseases (total of 123 diseases) and establish a mechanism to encourage investigations and research on understanding the current situation at a committee on measures against specific diseases. Efforts will continue to be made to facilitate the establishment and dissemination of treatment methods through promoting investigations and research on intractable diseases. Additional efforts will be made to promote community life support for patients with intractable diseases through promoting intractable disease consultations and the support center program that was established in FY 2003.

In February 2005 the first case of vCJD (variant Creutzfeldt-Jakob disease) was discovered in Japan. In response, efforts are being made to enhance the CJD surveillance system.

2. Measures against Rheumatism and Allergic Diseases

In order to implement comprehensive and systematic measures against rheumatism and allergic diseases in the future, the “Direction of Measures against Rheumatism” and “Direction of Measures against Allergic Diseases” were formulated, and disseminated to prefectures and related organizations in promoting the three principles of “securing a system to provide medical care”, “securing a system to provide information and consultations”, and “promoting research and development”.

With regard to “securing a system to provide medical care”, “Operation Zero Asthma Death” has been implemented since FY 2006 with the aim of decreasing the number of deaths caused by asthma. With regard to “securing a system to provide information and consultations”, in addition to improving training for nurturing consultants, dissemination and enlightenment efforts have been made, which includes holding symposiums, and establishing allergy consultation centers starting 2007. With regard to “promoting research and development”, efforts are being made to promote research on clarifying the cause and symptoms of the disease and developing treatment methods.

3. Promotion of Measures against AIDS (Acquired Immune Deficiency Syndrome)

The Joint United Nations Programme on HIV/AIDS (UNAIDS) estimated the number of people infected with the Human Immunodeficiency Virus (HIV) to be 33.2 million worldwide at the end of 2007. The region in which HIV is the most rapidly spreading is Sub-Saharan Africa but is also rapidly increasing in Eastern Europe, Central Asia, and East Asia. The infection has the trend of increasing in East Asia, which includes Japan.

The total number of reported HIV infected/AIDS patients in Japan exceeded 1,000 for the first time in 2004. By 2007 the number had reached 1,500 and was the highest ever with the total reported number of HIV infected persons being 9,426 and total number of AIDS patients 4,468 (1,438 cases due to blood coagulation factor products is excluded from each number). The characteristics of the trend with the infection is that the rate of increase of newly infected persons continues to grow, has an increasing trend in local cities, the percentage of people in their twenties and thirties is high, and 90 percent of the cause of infection is through sexual contact, with homosexual contact between men increasing in particular. Further improvements and enhancement of measures are needed therefore to cope with the situation.

In consideration to that and with respect to the “Report of the Study Group on Revision of Specific Infectious Disease Prevention Guidelines Regarding Acquired Immune Deficiency Syndrome” that was compiled in June 2005, the revised “Specific Infectious Disease Prevention Guidelines Regarding Acquired Immune Deficiency Syndrome” (so-called AIDS prevention guidelines) was enforced on April 1, 2006.

This guideline requests that comprehensive measures related to prevention and medical care be taken with respect being paid to the human rights of HIV infected, and AIDS patients in cooperation between the government, local governments, and NGOs which includes medical professionals and patients groups. These measures shall mainly focus on 3 important areas (① dissemination, enlightenment, and education, ② improved examination and consultation systems, ③ reconstruction of the medical care system), and include such measures as establishing a core hospital system to promote the establishment of a comprehensive medical care system within prefectures.

4. Solving Hansen’s Disease Issues

The “Act on Repealing the Leprosy Prevention Act” was enforced in April 1996 and support for the former residents of Hansen’s disease sanatoria with the necessary recuperation and rehabilitation. Subsequently, patients and former patients sued the national government in Kumamoto and other cities. The Kumamoto District Court handed down a juridical judgement that the plaintiffs had won a favourable verdict in May 2001. The government decided not to lodge an

intermediate appeal with the court, and instead announced a “Colloquy by the Prime Minister on the Early and Full-Scale Solution of Hansen’s Disease Problems” on May 25, 2001. Furthermore, the “Act on Payment of Compensation, etc. to Inmates of Hansen’s Disease Sanatoria, etc.” (hereinafter referred to as the Indemnity Law) was promulgated and enforced on June 22, 2001, under which compensation is being made to former residents of Hansen’s disease sanatoria.

On December 25, 2001, the Ministry of Health, Labour and Welfare and representatives of patients and former patients agreed upon the “Matters Confirmed at the Conference on Measures for Hansen’s Disease Problems”. Accordingly, the Ministry will take measures for the restoration of their honor and promotion of their welfare, in addition to traditional measures.

In addition to reconciliation effected before the court, compensation has been made that includes “Benefits for People Who Were in the National Hansen’s Disease Sanatoria” program in establishing a living base for them, and the “Reburial Cost for the Diseased in the National Hansen’s Disease Sanatoria” program for use in returning the honor of the dead since FY 2002, and the “Gratuity for People Who Were Not in National Hansen’s Disease Sanatoria” program for patients and former patients who had never actually been in sanatoria, for their stable, comfortable and normal social lives since FY 2005.

To promote public awareness with appropriate knowledge of the disease, nationwide symposiums have been held since FY 2004. In addition, as part of dissemination and enlightenment measures to restore their honor and remove prejudice and discrimination against patients and former patients, the “National Hansen's Disease Museum” was reopened in April 2007.

In February 2006 the "Act on Payment of Compensation, etc. to Inmates of Hansen's Disease Sanatoria, etc." was revised to include people who used to be in Hansen’s disease sanatoria established abroad before the end of the war in 1945 (specified by the Minister of Health, Labour and Welfare) as recipients of the compensation. At present, the Rakuseiin Hospital (Taiwan), Sorokto Hospital (South Korea), and 4 sanatoria established in the South Sea Islands (Palau, Yap, Saipan, and Jaluit) have been specified and efforts are being made for the early and complete resolution of the Hansen’s disease problems.

Furthermore, the “Act on Promotion of the Resolution of Hansen’s Disease Issues” was approved at a regular Diet session in June 2008 to promote resolution of the Hansen’s disease Issues. The law contains provisions such as allowing community residents to utilize national Hansen’s disease sanatoria and dissemination of appropriate knowledge on Hansen’s disease as a measure to restore the honor of patients and former patients.

5. Appropriate Implementation of Organ Transplantations

(1) Implementation of Organ Transplantations

The Law on Organ Transplantations (hereinafter referred to as the Organ Transplantation Law)

was enforced in October 1997. The law permits transplantation of organs such as eyeballs (corneas), hearts, lungs, livers and kidneys from brain-dead donors.

From enforcement of the law to the end of June 2008, 71 people had been judged as brain-dead in compliance with the Organ Transplantation Law. In FY 2007 9 cases of heart transplantations from 9 donors, 7 cases of lung transplantations from 7 donors, 11 cases of liver transplantations from 10 donors, 206 cases of kidney transplantations from 113 donors, 10 cases of pancreas transplantations from 10 donors (of kidney and pancreas transplantations, 6 cases had kidneys and pancreases transplanted at the same time) and 1,542 cases of cornea transplantations from 995 donors had occurred, including transplantations from both brain- and heart-dead donors.

As of the end of June 2008, patients waiting for organ transplantations consisted of those needing hearts (105), lungs (121), livers (210), kidneys (11,507), pancreases (149), small intestines (2) and corneas (2,933).

In the meantime the Minister of Health, Labour and Welfare has held “Examination Meetings on Organ Transplantation Cases from Brain-Dead Donors” and invited both learned and experienced people to them. At the meetings the situation with lifesaving treatments of donors, legal brain death judgements, and intermediary work conducted by the Japan Organ Transplant Network are being examined.

(2) Recent Movements towards the Promotion of Organ Transplantations

In order to provide more opportunities for people to indicate their willingness to donate organs a column to indicate that willingness can be added to the insurance cards issued by health insurance societies and the National Health Insurance scheme. Insurance cards of government-managed health insurance with a column to indicate that willingness have been issued since January 2007. In addition, a Japan Organ Transplant Network started operating an organ donation willingness registration system in March 2007.

In the meantime, 2 drafts of the “Draft Legislation to Amend the Law on Organ Transplantations” in revising the requirements for organ donations in case of brain-death were presented at a regular Diet session in 2006 by members of the Diet with another at an extraordinary Diet session in 2007, all of which are currently still under examination.

(3) Transplantation of Hematopoietic Stem Cells

Transplantations of hematopoietic stem cells, such as from bone marrow and umbilical cord blood, have been implemented as a treatment method for leukaemia, aplastic anemia or the like. With such transplantations, it is essential that the type of leucocyte (HLA type) of the patient matches that of the donor, or that of stored umbilical cord blood, which means that an adequate

number of donors must be secured for transplanting hematopoietic stem cells to all the patients that are in need of them.

In light of this, a public bone marrow bank project has been implemented since FY 1991, with a public umbilical cord blood bank project having been in operation since FY 1999 for transplanting hematopoietic stem cells between non-biologically related patients and donors. As of January 2008 the number of registered donors at the public bone marrow bank had reached the objective of 300 thousand. Further efforts are being made to promote donor registrations for patients in need of bone marrow transplantations. In addition, the Committee on Hematopoietic Cell Transplantations within the Subcommittee on Measures against Diseases, Health Sciences Council are discussing measures that will need to be taken in the future with hematopoietic stem cell transplantations.

6. Countermeasures against Pandemic Influenza

Pandemic influenza emerges when an influenza virus which has not infect humans transforms itself and becomes infectious from human to human. In the past, pandemic influenza such as Spanish influenza and Asian influenza have emerged in a 10 to 40 year cycle, causing worldwide pandemics.

The highly pathogenic avian influenza, which is highly pathogenic to birds, was prevalent mainly in Southeast Asia since November 2003 but has now spread to Europe and Africa. At the same time, human cases of H5N1 have been identified in Indonesia, Egypt, and Turkey. The number of patients totalled 385 (as of June 19 2008, 243 have deceased) and is increasing. Thus, the emergence of pandemic influenza is currently of great concern.

“The National Action Plan against Pandemic Influenza” was established by the Japanese government in December 2005. Based on that plan, guidelines are being written by Expert Committees and the national government along with related ministries and agencies is tackling against pandemic influenza Details are as given below.

In the mean time, the latest information on pandemic influenza is provided on the websites of the Ministry of Health, Labour and Welfare and National Institute of Infectious Diseases.

Content page of the Ministry of Health, Labour and Welfare:

<http://www.mhlw.go.jp/bunya/kenkou/kekkaku-kansenshou04/index.html>

Content page of the National Institute of Infectious Diseases:

http://idsc.nih.go.jp/disease/avian_influenza/index.html

(1) Intension of measures against Pandemic Influenza based on the Infectious Disease Law and Quarantine Law

In order to develop a legislation for minimizing the effect of a pandemic influenza and to promptly

and fully implement the necessary measures in the period of non-pandemic as well as pandemic, the “Draft Law to Amend the Law Concerning the Prevention of Infectious Diseases and Medical Care for Patients Suffering from Infectious Diseases and the Quarantine Law” was presented at a regular Diet session in 2008. Concrete legislation is as below:

- Categorizing avian influenza (H5N1) as infectious disease type 2 and legally ensuring for measures such as hospitalization
- Newly categorizing pandemic influenza in both the Infectious Disease Law and Quarantine Law in order to enable to take measures such as quarantine and hospitalization immediately after the outbreak of a pandemic influenza
- Developing a provision asking those suspected of infection to restrain outings, and allowing non-medical facilities to be utilized for detention, as preventing the spread of infection based on the consideration of the high infectiousness of pandemic influenza

The draft law was approved on April 25, 2008, promulgated on May 2, and enforced on May 12.

(2) Securing Anti-Influenza Virus Drugs

In the case of a nation-wide spread of pandemic influenza, the number of outpatients is estimated at 25 million. Hence, in accordance with the action plan, oseltamivir phosphate (trade name: Tamiflu), a therapeutic drug for influenza, has been stockpiled for a total of 28 million people for use by the nation and prefectures and in distribution, that include a stockpile of 3 million for preventative use. They had been secured by FY 2007.

Since the virus could acquire resistance to oseltamivir phosphate (Tamiflu), stockpiles for 1.35 million people of zanamivir hydrate (trade name: relenza) had been secured by FY 2007 for risk management purpose.

(3) Development of Vaccines for Pandemic Influenza

If a safe and effective vaccine against pandemic influenza is put to practical use, it is expected to have a very beneficial effect for preventing the onset and development of infection. To enable a prompt supply being at the early stage of pandemic influenza, pre-pandemic vaccines by 2 companies have been approved under the Pharmaceutical Affairs Law in October 2007.

In addition, pre-pandemic vaccines have been stockpiled for 10 million people (Vietnamese strain and Indonesian strain) in FY 2006 and for 10 million people (Anhui strain of China) in FY 2007 so that medical staff and people who maintain critical social functions can get the vaccines for emergency use.

(4) Exercises for Pandemic Influenza

In November 2007, the 3rd integrated exercise was conducted and all related ministries agencies, a quarantine station at an airport and a local government were participated. This exercise was carried out in the form of desktop based on assuming a widespread case scenario of a pandemic influenza. The operations and coordination between related ministries, agencies and the local government were examined.

In addition, quarantine operations including delivery patients have been drilled by the quarantine station and the local government. The outcome of the exercises will be reflected in their preparedness plans. Moreover, carrying out additional exercises are taken into consideration in order to prepare for prompt and adequate actions in the period of a pandemic influenza.

7. Promotion of Countermeasures for Atomic Bomb Survivors

Comprehensive health/medical care and welfare measures to support atomic bomb survivors are being promoted in accordance with the Law Concerning Atomic Bomb Survivors Relief. The measures include ① health checkups, ② a public-funded medical care system, ③ a supply of a special medical allowance, a special allowance, a health management allowance, a health allowance, a long-term care allowance, and to help with funerals, ④ counselling, daily home-visit living support, and welfare services that include institutional care at residential facilities for the survivors, ⑤ promotion of research and study at the Radiation Effects Research Foundation, and ⑥ management of the Hiroshima and Nagasaki National Peace Memorial Halls for Atomic Bomb Survivors.

Regarding certification of atomic bomb sickness Prime Minister Abe (at the time) gave directions in August 2007 to “discuss and review the issue based on the judgement of experts”. Accordingly, the “Study Group on Certification of Atomic Bomb Sickness”, consisting of a group of experts, have been held by the Health Service Bureau of the Ministry of Health, Labour and Welfare since September 2007 and a report compiled on December 17, 2007. In addition, the “Project Team on Countermeasures for Atomic Bomb Survivors” was established by government parties and suggestions compiled on December 19, 2007. In consideration of that the “New Certification Guidelines” for atomic bomb survivors was compiled by the Subcommittee on Atomic Bomb Survivors Medical Care of the Examination Committee for Certification of Sickness and Disability in March 2008. Certifications have been made in accordance with these guidelines since April 2008.

Support projects for atomic bomb survivors living abroad include financial support for transportation expenses when returning to Japan to apply for an A-bomb Survivors' Certificate or to receive medical treatment as well as for medical expenses when receiving medical treatment in the

country in which they live. In addition, atomic bomb survivors living abroad can apply for a Health Management Allowance through the consular in the country in which they live in order to avoid having to return to Japan. Furthermore, a Draft Law to amend the Law Concerning Atomic Bomb Survivors Relief was presented by members of the Diet and approved at a regular Diet session in 2008 that enables atomic bomb survivors living abroad to apply for A-bomb Survivor Certification.

8. Comprehensive Promotion of Measures against Hepatitis

The number of patients infected with the hepatitis virus is estimated to be 1.1 to 1.4 million for hepatitis B and 2 to 2.4 million for hepatitis C. Many of these patients do not have subjective symptoms, and thus are unaware that they have been infected and hence have received no treatment which has resulting in it progressing to more severe diseases such as cirrhosis of liver and liver cancer.

In consideration of this, promoting its early discovery and early treatment as well as maintaining and improving patients' health while helping to alleviate any anxieties they may be facing through a higher level of treatment is considered to be of the utmost importance with viral hepatitis. Since the formulation of the "Emergency Comprehensive Measures against Hepatitis C" in FY 2002 comprehensive measures such as:

- ① enhancing dissemination and enlightenment activities, counselling, and guidance for the people concerned
- ② conducting hepatitis virus examinations utilizing various health examination programs
- ③ research and development on preventive and treatment methods through the "Emergency Comprehensive Measures against Hepatitis C"
- ④ establishment of a treatment system in cooperation between core hospitals for liver disease treatment in prefectures

have all been implemented.

In FY 2007 a measure to further promote hepatitis virus examinations was taken in order that people can receive the examination free of charge at medical institutions consigned by prefectures in addition to the free examinations provided at health care centers.

In addition, prefectures commenced implementation of free medical subsidy system for interferon treatment for hepatitis B and hepatitis C in FY 2008. Effective treatment can completely cure people of viral hepatitis while preventing future cirrhosis of liver or liver cancer, and hence the promotion of early treatment will suppress the burden on patients at a fixed fee related to their income.

In FY 2008, new comprehensive measures will be further promoted mainly through medical fee

subsidies (Figure 1-7-1) (for more details on hepatitis C lawsuits refer to Section 1 of Chapter 9).

Figure 1-7-1 Promotion of Measures against Hepatitis

[Direction of Measures]

- Reducing the financial burden through preventing its progression to liver cancer and effective promotion of hepatitis treatment
- Comprehensive and further promotion of examinations, treatment, dissemination, and research
- Steady implementation of reducing the number of people who have not had examinations, even distribution of hepatitis medical care, and dissemination and enlightenment of the appropriate knowledge

1. Creating an Environment for Promoting Interferon Treatment

- Medical Fee Subsidies for Interferon Treatment
 - Providing medical fee subsidies for hepatitis B and hepatitis C patients who are in need of interferon treatment

2. Promotion of Hepatitis Virus Examinations

- Promotion of Hepatitis Virus Examinations and Establishment of an Examination System at Health Care Centers
 - Establishment of an examination system that takes into consideration the accessibility through consignment of medical institutions to promote the number of people who have not had examination being reduced
- Hepatitis Virus Examinations being Conducted by Municipalities and Health Care Insurers

3. Promotion of Health Care, Promotion of Safe and Reliable Hepatitis Treatment, and Ensuring Care for Cirrhosis of Liver and Liver Cancer Patients

- Expanding the Establishment of a Medical Care System
 - Establishment of “core hospitals for liver disease treatment” in prefectures in providing a system for use in making consultations available for patients and carriers (consultation centers), and creating National “Hepatitis Core Medical Institutions (tentative name)” that can support core hospitals
- Physical and Mental Care for Cirrhosis of Liver and Liver Cancer Patients and Providing Training for Doctors

4. Dissemination of the Appropriate Knowledge and Understanding

- Dissemination of the Appropriate Knowledge in Various Sectors including Education, Work, and Community

5. Promotion of Research

- Research and Development of New Treatment Methods for Liver Diseases
 - Promotion of clinical research including application of anti-virus treatments according to a patients' symptoms and measures against any side effects of that treatment
- Promotion of Development, approval under the Pharmaceutical Affairs Law, and Application of Insurance for Liver Disease Treatment
 - Promotion of rapid regulatory approval and insurance application according to the situation with the research and development of therapeutic drugs