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Digital Healthcare 2022

Japan: Trends & Developments

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Trends and Developments

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General

Currently in Japan, people aged 65 years and older make up approximately 30% of the population. Japan's ageing population is unprecedented and poses serious societal problems, such as a relatively decreasing labour force and increasing social security costs. In recent years, there have been moves towards resolving these problems using technologies such as artificial intelligence (AI) and the internet of things (IoT). As a result, new businesses and start-ups have been emerging that are creating new technologies and services in this area.

These developments were intensified because of the COVID-19 pandemic. As in other countries, since 2020 remote working and non-contact activities have become routine in Japan and, therefore, the practical application of digital health technologies has been accelerating.

Progress was made in 2021 in various digital health areas, such as the expansion of remote medical care, the increase in healthcare-related apps and utilisation of healthcare data.

Expansion of Remote Medical Care

Background

Previously in Japan, medical services were administered face-to-face. Remote medical care was regarded as a supplement to face-to-face treatment and its use was limited. Face-to-face guidance on the administration of medication had been mandatory. However, in recent years, in addition to the development of information and communication devices, there has been a temporary relaxation of related regulations as a response to the increased demand for online medical treatment and online medication guidance during the COVID-19 pandemic. This has resulted in the widespread use of telemedicine and online medication guidance.

Telemedicine

The limitations of Japanese telemedicine have been discussed for some time in relation to Article 20 of the Medical Practitioners' Act, which prohibits physicians from providing medical treatment without an examination. In this context, the Ministry of Health, Labour and Welfare (MHLW) formulated the Telemedicine Guidelines in March 2018, stipulating the minimum compliance requirements for telemedicine and clearly stating that compliance with the Guidelines does not violate Article 20 of the Medical Practitioners' Act.

These Guidelines specify that an initial medical consultation is to be conducted in person, which did not necessarily lead to the expansion of its use. However, the MHLW revised the Guidelines in January 2022 ("Telemedicine Amended Guidelines") in response to the increased use of telemedicine during the COVID-19 pandemic. It widely approved the use of telemedicine from the initial treatment, even as the pandemic is coming to an end.

According to the Telemedicine Amended Guidelines, telemedicine from the first examination is permitted in the following cases:

- when the first examination is conducted by a "family physician" (a physician who has an existing direct relationship with the patient,

such as one who has been regularly and directly treating the patient);
- when medical information, such as the medical history, is available and the physician determines it possible to provide telemedicine, in accordance with the patient's symptoms; and
- when a physician consults a patient before treatment (ie, when a physician checks the patient's symptoms and medical information before formal medical treatment) in cases where the family physician is absent or other specific situations.

However, according to the Telemedicine Amended Guidelines, there are certain limitations, such as when symptoms are not suitable for an initial treatment by telemedicine or a medicine is prohibited from being prescribed at an initial examination. In addition, medical treatment solely by telephone or by an exchange of letters or documents is not permitted. Also, treatments are limited to those who have both visual and aural senses.

Japan has a universal health insurance system that allows all residents to receive insured medical care at a low cost. Previously, there were only a limited number of diseases that could be treated by telemedicine that were covered by insurance, and medical fees were lower than those for face-to-face treatment. However, with the revision of medical fees in 2022, limitations on the number of diseases that could be treated were eased, and medical fees became almost the same as those for face-to-face treatment. It is expected, therefore, that there will be an increased use of telemedicine in the future.

Telemedicine itself can only be provided by a physician, but in cases where the content of the advice does not include medical judgment, such advice may be given by a person who is not a physician without the application of the Medical Practitioners' Act and the Telemedicine Guidelines. Such health consulting services are positioned as a preliminary step to telemedicine. They remain in high demand to help in the early detection of diseases and there are low barriers to entry into the business.

Online medication guidance

In Japan, the separation of medical and dispensary practices has been adopted. Under this system physicians prescribe drugs and pharmacists dispense the prescribed drugs and sell them to patients. Prior to the revision of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices ("Pharmaceutical and Medical Device Act") in 2020, the proprietor of a pharmacy had to provide face-to-face guidance by a pharmacist when selling or giving drugs prescribed by a physician so that the patient could be instructed in the proper use of the drugs.

While the revision of the Pharmaceutical and Medical Device Act made it possible to provide online medication guidance, it did not become popular because there were many restrictions, such as guidance only being allowed for prescriptions provided for telemedicine or home-visit medical care. However, in response to the high demand for online medication guidance during the COVID-19 pandemic, the Ordinance for Enforcement of the Pharmaceutical and Medical Device Act was revised. From April 2022, the cases for which online medication guidance can be provided have been expanded so that:

- online medication guidance is available at first-time treatment;
- online medication guidance is available for all prescriptions and is not limited to prescriptions issued during telemedicine or home visits; and

- in addition to the drugs previously prescribed, online medication guidance is available for all drugs, in principle.

However, with telemedicine, video and audio communication is required; voice-only (telephone) support is not permitted.

Example of a telemedicine system

Medley, Inc. provides the "Clinics Telemedicine System," Japan's largest telemedicine system in the medical platform sector. One of its applications allows for online appointments, prediagnostic interviews, video chat examinations, medication guidance, credit card payments, and drug/prescription delivery all at once, allowing patients to continue receiving treatment without leaving their homes. This reduces the burden of outpatient visits, improves the rate of continuing treatments and prevents secondary infections at hospitals.

It is expected that online medical services, in conjunction with the provision of test kits and image analysis systems, will increase in the future.

Increase in Healthcare-Related Apps

Background

In 2020, a therapeutic app made by Cure App, Inc. was approved as a medical device program for the first time in Japan. This app is for helping nicotine-dependent patients to stop smoking and is covered by insurance. Since then, the number of applications for pharmaceutical approval of therapeutic apps has been increasing. Moreover, although there is a functional overlap with therapeutic apps, the development of recording apps, which are provided as a preparatory stage for the development of therapeutic apps, is rapidly increasing because, under the Pharmaceutical and Medical Device Act, licences and approvals are not required.

Therapeutic apps and symptom recording apps

Therapeutic apps are used for the "treatment" of a specific disease in a medical setting and may be circumscribed by the following:

- as "medical device programs," they must be developed, manufactured and sold in accordance with the Pharmaceutical and Medical Device Act;
- approval to manufacture and sell them in Japan as new medical devices must be acquired from the MHLW after clinical trials have been conducted, which can take several years and be costly;
- as a long period of time is required until the apps are covered by insurance, it can take much time and money until they reach the market.

Symptom recording apps are used for "managing the health condition" of a healthy person and "recording symptoms" of a patient. A typical app is one that is used for recording health information, such as weight and blood pressure, daily. Their characteristics are as follows:

- they cannot express the therapeutic effects of the disease;
- since they are not "medical device programs," procedures based on the Pharmaceutical and Medical Device Act are not required; and
- their price can be freely set since they are not covered by insurance.

Such "medical device programs" are programs (software functions) that are intended to diagnose, treat, or prevent diseases and are likely to affect a person's health in the event of a malfunction Their manufacture and sale is regulated by procedures based on the Pharmaceutical and Medical Device Act. Therefore, even if they are defined as symptom recording apps, they may correspond to medical device programs,

depending on their functions and their proposed effects. It will be necessary to confirm whether such apps correspond to medical device programs when they are provided.

Because the criteria for determining whether a program is a medical device program was unclear, in March 2021 the MHLW established guidelines on the applicability of the term "medical device" to a program. According to these guidelines, it is highly likely that a program corresponds to a medical device program in the following cases:

- if the diagnosis, treatment or prevention of disease is intended;
- if the candidate diseases and risk of disease are displayed based on input information; or
- if the program corresponds to Class II or higher when judged based on the Global Harmonization Task Force rules.

In recent years, many companies have been providing symptom recording apps as a preparatory stage for the development of therapeutic apps, but sufficient attention must be paid to whether they can be defined as medical device programs.

Example of a therapeutic app

In addition to the above-mentioned smoking cessation application, Cure App, Inc. received pharmaceutical approval for a therapeutic app for hypertension (Accepted name: Hypertension Treatment Assistance Program) in April 2022. This is the first case in Japan in which pharmaceutical approval was obtained for the software itself, and it is the world's first pharmaceutical approval for a therapeutic app in the field of hypertension. The company is aiming to accomplishdigital therapies that support improving lifestyles through apps for hypertension, rather than relying solely on drugs, and is aiming for insurance coverage and launch by the end of 2022.

It is expected that various therapeutic apps and symptom recording apps will be introduced in the Japanese market in the future.

Utilisation of Healthcare Data

Background

In recent years, with the improvement of individual health awareness, the collection and use of information (healthcare data) such as personal health status and medication records, including medical treatment, examinations, prescription, vital physiological data (such as walking rates and pulse rates) obtained by a wearable device and clinical trial data, have been widely practised. As this is a global trend, personal data is frequently transferred overseas, creating a variety of businesses in this area. Accordingly, the Act on the Protection of Personal Information of Japan was amended and came into effect in April 2022 (revised Act on the Protection of Personal Information) in order to respond to the increased need for the protection of personal information and the utilisation of personal information across borders.

Healthcare data and the revised Act on the Protection of Personal Information

Under the Act on the Protection of Personal Information, "special care-required personal information" is defined as information based onmedical history, results of medical examinations, and the fact that guidance on medical treatment, or dispensing of medicine has been provided based on such results. It is necessary to obtain the consent of the individualfor the use of such data.

In addition, regardless of whether or not such information is special-care-required personal information, it is necessary to obtain the consent of the individual when providing such personal data to a third party, in particular, when the third party is located in a foreign country. In cases where personal data is provided through

entrustment, the consent of the individual must be obtained before the transfer overseas of such data.

Although the above regulations have been in force, the revised Act on the Protection of Personal Information requires that when obtaining consent from the individual for the overseas transfer of personal data, information concerning the system for the protection of personal information in the recipient country, and measures for the protection of personal information taken by the recipient third party shall be provided to the individual, except in the following cases:

- when the recipient country is a country that is recognised by the Personal Information Protection Commission as having a personal information protection system that is on level with that of Japan (currently, the EU and the UK); and
- when the recipient third party has developed a system necessary for continuously taking measures equivalent to the measures to be taken by a business operator handling personal information in Japan (equivalent measures).

In the case of the first point, measures necessary to ensure the continuous implementation of equivalent measures by the recipient are required, and in the event of a request by the individual, the provider shall be obliged to provide the them with information on such measures. Therefore, it is preferable to prepare the information to be provided in advance.

Response to the revised Act on the Protection of Personal Information

Healthcare data, especially information obtained in clinical trials, is often registered in overseas databases such as ClinicalTrials.gov, and since it is highly likely that overseas third parties will obtain such information, providers handling healthcare data will need to respond to the above-mentioned revisions to the Act on the Protection of Personal Information. In addition to clinical trial data, when personal data is stored on overseas servers, it is possible that such acts may be deemed as the provision of personal data overseas, and therefore, such providers will also need to respond to the aforementioned revisions.

Remote Clinical Trials

Recently, in Japan, "remote clinical trials," have begun to increase. A remote clinical trial is clinical research for approval of a drug or medical device, in which a patient participates remotely, such as from home. Although the introduction of remote clinical trials had not progressed because of concerns about cost-effectiveness, the spread of COVID-19 increased the tendency of people to stay-at-home and, thereby, increased the necessity for remote trials.

Participants can use smartphone apps to partially conduct clinical trials at nearby medical institutions or at home, saving travel time. Pharmaceutical companies can also expect a reduction in the costs and time of clinical trials, making the development of new drugs more efficient.

In the spring of 2020, the MHLW released guidelines on how to proceed with clinical trials under the COVID-19 pandemic and by presenting a certain concept of remote clinical trials, made it easier for pharmaceutical companies to introduce remote clinical trials. However, while clinical trials are required to be explained and agreed to in writing, in accordance with the Good Clinical Practice standards, no clear rules for remote clinical trials have currently been established. In the near future, the MHLW intends to compile guidelines on the elements to be considered when conducting remote clinical trials.

Medical AI

In recent years, the use of artificial intelligence (AI) has gradually resulted in more efficient work, collection and utilisation of medical data, reduction of the burden on patients and provision of information in the healthcare setting in Japan. Previously, AI-organised diagnostic interview information and AI-analysed medical images have been the main components of medical AI. Although approximately 20 medical devices have been officially approved by the MHLW, most of them are medical devices that analyse images by AI.

According to the notification from the MHLW in 2018, when providing treatment using AI medical devices, it is necessary for a physician to be the primary provider of diagnostic treatment and for a physician to be responsible for making the final decision. Therefore at present, AI is only a tool for presenting information on the medical process and is not permitted to make definitive diagnoses for patients. In the future, the development of AI that can reproduce physician examinations, such as visual examinations, auscultation and palpation, is anticipated.

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TMI Associates was established on 1 October 1990 and has grown rapidly to become a full-service law firm that offers comprehensive legal services of the highest quality. TMI Associates provides support in the digital health and life sciences field. The firm's healthcare practice group has supported a wide range of clients, including domestic and global healthcare start-ups, universities, pharmaceutical and medical device companies, venture capital and governmental organisations. TMI is proactively engaged in all aspects of the field, such as advising on pharmaceutical regulations, IP acquisition and utilisation, conducting legal and IP due diligence for M&A and IPO, drafting and negotiating licence agreements and assisting patent litigations. The firm is in close contact with the Ministry of Health, Labour and Welfare, to which its attorneys have been seconded. TMI Associates examines risks based on its precise grasp of the practical operation and interpretation of relevant regulations and guidelines in the field.

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Yoshiyuki Inaba is a senior partner at TMI Associates and has more than 45 years' experience. He heads the intellectual property group, utilising his expertise in patent and trade mark prosecutions and enforcement to oversee the daily management of each client's IP portfolios to ensure that the client's interests are fully covered. He also handles and supervises patent and trade mark lawsuits at both the District and IP High Court levels, as well as conducting invalidation procedures at the Japan Patent Office. In addition, he is active in negotiations for clients, including those regarding licensing, transfers and general co-operative arrangements.

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