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**A Re-examination of Issues Related to the Relief System for Injury  
to Health with Vaccination and the Report on Suspected Adverse Reactions**

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# A Re-examination of Issues Related to the Relief System for Injury to Health with Vaccination and the Report on Suspected Adverse Reactions<sup>†</sup>

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## Abstract

This paper examines the Relief System for Injury to Health with Vaccination and the Report on Suspected Adverse Reactions. Specifically, regarding the Relief System for Injury to Health with Vaccination, we analyze data obtained through public information disclosure requests submitted to the 23 wards of Tokyo and derive statistics such as the average number of days required from application to approval or rejection, as well as the distribution of these durations. In addition, we investigate the relationship between the presence or absence of a Report on Suspected Adverse Reactions and the approval or rejection outcomes under the relief system.

Furthermore, regarding the Report on Suspected Adverse Reactions, this paper presents the results of a survey conducted across all 47 prefectures in Japan on which items of information related to suspected adverse reactions are disclosed. The Relief System for Injury to Health with Vaccination and the Report on Suspected Adverse Reactions are important mechanisms for promoting vaccination policies. Examining these systems is therefore highly meaningful.

**Keywords :** Related to the Relief System for Injury to Health with Vaccination, Report on Suspected Adverse Reactions

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<sup>†</sup> This paper was prepared with the benefit of information provided by many individuals, which helped clarify the issues addressed herein. The author also received assistance in conducting certain public information disclosure requests. The author wishes to express sincere gratitude to all those who contributed. Any remaining errors are solely the responsibility of the author. The Japanese version is <https://drive.google.com/file/d/1sA5steoEX40alfdm8I2BUgoMwQgOycTU/view>.

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## 1. Introduction

The purpose of this paper is to examine the Relief System for Injury to Health with Vaccination and the Report on Suspected Adverse Reactions.<sup>1</sup> Specifically, with regard to the Relief System for Injury to Health with Vaccination, we examined the status of applications under the relief system and the number of days required until approval or rejection, based on data obtained through public information disclosure requests submitted to the 23 wards of Tokyo. Previous studies have also analyzed data from municipalities in the Hanshin area and from Aichi Prefecture and have compared applications related to COVID-19 vaccination with those related to other routine vaccinations using data from Hyogo Prefecture. By analyzing multiple regions, regional characteristics can be identified; in this sense, focusing on the 23 wards of Tokyo as the subject of analysis is meaningful.<sup>2</sup>

Turning to the Report on Suspected Adverse Reactions, the adverse reaction report forms contain chronological information on symptoms following vaccination. However, the content disclosed in these reports is not necessarily uniform nationwide. This paper presents the results of a survey conducted across all 47 prefectures regarding which items of information can be disclosed. Only a limited number of prefectures disclose items such as summaries of symptoms. Regional disparities in the disclosure of information from the Report on Suspected Adverse Reactions directly translate into information gaps, which in turn lead to regional disparities in access to vaccination-related information.

Moreover, five years have passed since the start of COVID-19 vaccination, and various issues have come to the surface. These include, for example, problems related to the retention of medical records and issues concerning administrative review requests (that is, problems arising when applications under the relief system are rejected). Although such issues can be

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<sup>1</sup> The Relief System for Injury to Health with Vaccination is a scheme under which benefits, such as medical expenses and medical allowances, are provided when the Minister of Health, Labour and Welfare determines that a health injury was caused by vaccination. See Ministry of Health, Labour and Welfare, “On the Relief System for Injury to Health with Vaccination .”

<sup>2</sup> See Yasuoka (2024, 2025).

said to have occurred or could have occurred in previous vaccination programs, the COVID-19 vaccination appears to have brought them into sharper focus. This paper revisits and highlights the problems associated with the Relief System for Injury to Health with Vaccination and the Report on Suspected Adverse Reactions.

The structure of this paper is as follows. Section 2 presents an analysis of applications under the Relief System for Injury to Health with Vaccination based on data obtained through public information disclosure requests submitted to the 23 wards of Tokyo. Section 3 explains information disclosure related to the Report on Suspected Adverse Reactions. Specifically, it is based on a survey conducted by the author across all 47 prefectures regarding the extent to which information can be disclosed. This section also draws on materials prepared when the author provided opinions as an assistant to a certain city in connection with information disclosure. Section 4 provides concluding remarks, addressing issues related to the Relief System for Injury to Health with Vaccination, problems concerning the retention of medical records, and other issues that may arise not only at present but also in the future.

## **2. The Status of the Relief System for Injury to Health with Vaccination in the 23 Wards of Tokyo**

In order to examine the status of applications under the Relief System for Injury to Health with Vaccination related to COVID-19 vaccination in the 23 wards of Tokyo, the author began procedures in April 2025 to obtain the necessary data through public information disclosure requests submitted to each of the 23 wards. Although data materials were obtained from all wards by June 2025, some wards did not disclose certain items of information. As a result, the analysis was conducted under constraints that precluded a comprehensive examination of all 23 wards, necessitating instead an analysis limited to a subset of wards.

We first examine the number of days from the acceptance of an application by a ward to its submission to the Tokyo Metropolitan Government. Before presenting the analysis, we briefly describe the Relief System for Injury to Health with Vaccination. When individuals suffer adverse health effects as a result of vaccination, they may receive benefits, such as coverage of medical expenses, through the Relief System for Injury to Health with Vaccination. To apply, required documents—including medical records, receipts, and certificates of medical

consultation—must be submitted to the relevant municipality. These application materials are then forwarded to the Ministry of Health, Labour and Welfare via the Tokyo Metropolitan Government, where they are reviewed by the Disease and Disability Certification Review Board.

To assess whether benefits are being provided in a timely manner, we first focus on the number of days from the date on which applications are accepted by the wards to the date on which they are forwarded to the Tokyo Metropolitan Government. It should be noted that the benefits considered in this analysis include not only medical expenses and medical allowances but also other forms of compensation, such as lump-sum death benefits. For this analysis, data were obtained from 14 wards in Tokyo. The table below presents, from left to right, the average number of days and related statistics for these 14 wards.

The average number of days	182.97
The median number of days	162
The standard deviation of days	110.29

Table 1. Number of Days from Application Acceptance to Submission to the Tokyo Metropolitan Government in 14 Wards of Tokyo

(Data: June 2026. Author’s calculations. Number of observations: 473.)

Among the 14 wards, the shortest average number of days was 93.61, while the longest average was 241.91, indicating substantial variation across wards. It is also possible to derive a confidence interval for the population mean from the sample mean. The 95% confidence interval can be calculated as “sample mean  $\pm 1.96 \times \frac{\text{standard deviation}}{\sqrt{\text{sample size}}}$ .” Applying this formula yields an interval of  $182.97 \pm 5.07$  days.

Regarding the distribution of processing days, applications were grouped into 25-day intervals and the number of applications in each interval was plotted, yielding the following figure.

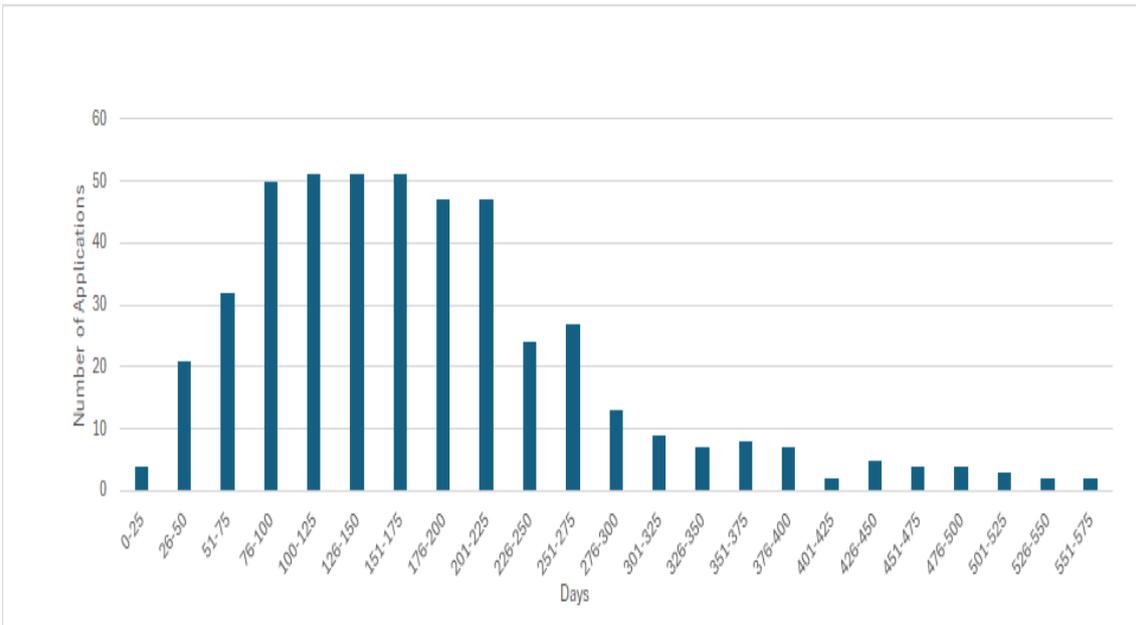


Figure 1. Distribution of Days from Application Acceptance to Submission to the Tokyo Metropolitan Government in 14 Wards of Tokyo

(Data: June 2025. Author’s calculations.)

Next, among the 23 wards of Tokyo, data on the number of applications were obtained for 20 wards. Using these 20 wards, we calculate the ratio of applications to population. The total population of the 20 wards is 7,862,615, and the number of applications is 797. Accordingly, the ratio of applications to population is 0.0101%, corresponding to approximately one application per 10,000 residents. It should also be noted that Tokyo has a relatively low aging rate (the proportion of the population aged 65 and over), at 19.41%, compared with the national average.<sup>3</sup>

We also examined whether the number of days from acceptance by the wards to submission to the Tokyo Metropolitan Government has decreased or increased over time. We initially hypothesized that this duration would shorten over time, as administrative authorities might be unfamiliar with the procedures at the outset but gradually improve efficiency through a form of learning by doing. While such a trend was indeed observed in some wards, the

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<sup>3</sup> Population data are described in the data section below.

opposite pattern—an increase in processing time—was identified in others. One possible explanation is that, as the number of applications declined over time, wards began to wait until applications accumulated to a certain extent before convening review committees, thereby delaying submission to the Tokyo Metropolitan Government.

Next, we examine the number of days from the application date to the date of approval or rejection. Due to data constraints, information for this period was available for 13 wards. The table below presents, from left to right, the average number of days and related statistics for these 13 wards in Tokyo.

The average number of days	520.18
The median number of days	513
The standard deviation of days	168.64

Table 2. Number of Days from Application to Approval or Rejection Decision in 13 Wards of Tokyo

(Data: June 2026. Author’s calculations. Number of observations: 386.)

With respect to the population mean, calculating the 95% confidence interval yields  $520.18 \pm 8.58$  days. For this distribution, applications were grouped into 50-day intervals and the number of applications in each interval was plotted, yielding the following figure.

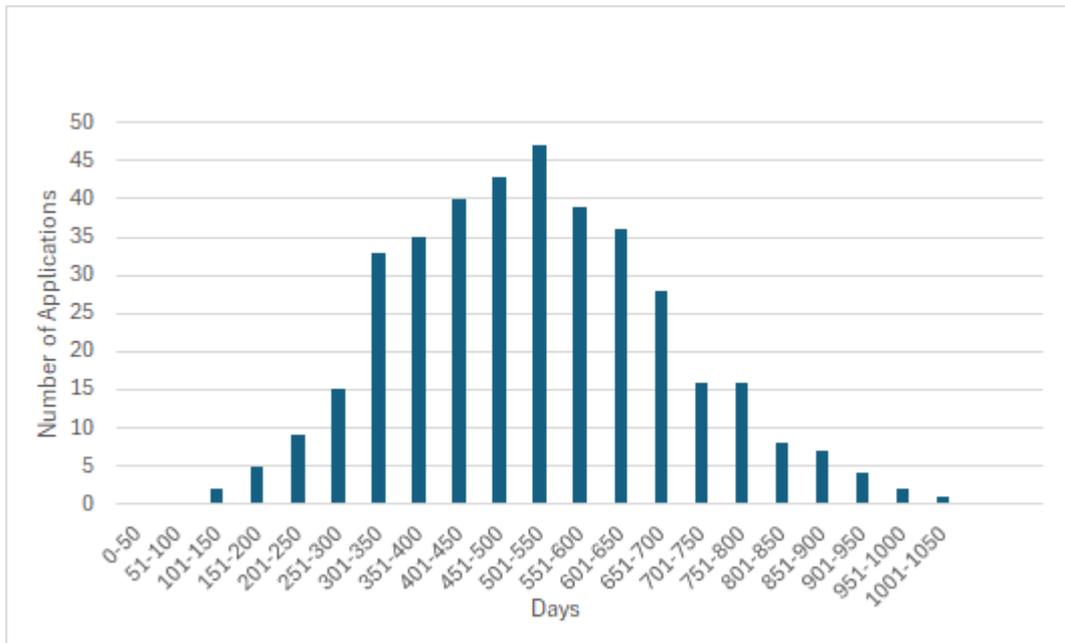


Figure 2. Distribution of Days from Application to Approval or Rejection Decision in 13 Wards of Tokyo

(Data: June 2025. Author’s calculations.)

Next, using data from 16 wards within the 23 wards of Tokyo for which outcomes of approval or rejection were available, we present the proportions of approved, rejected, and under review cases. Figure 5 illustrates this breakdown. As of June 2025, we had expected that the review process by the Disease and Disability Certification Review Board for applications under the relief system would have become faster to some extent; however, approximately 20% of cases remain undecided, with neither approval nor rejection determined. When the number of approved cases is calculated as a proportion of the total number of approved and rejected cases in these 16 wards, the approval rate is 74.6%. Moreover, approval rates vary across the 16 wards: among the available data, the lowest approval rate is 62.5%, while the highest is 84.21%.

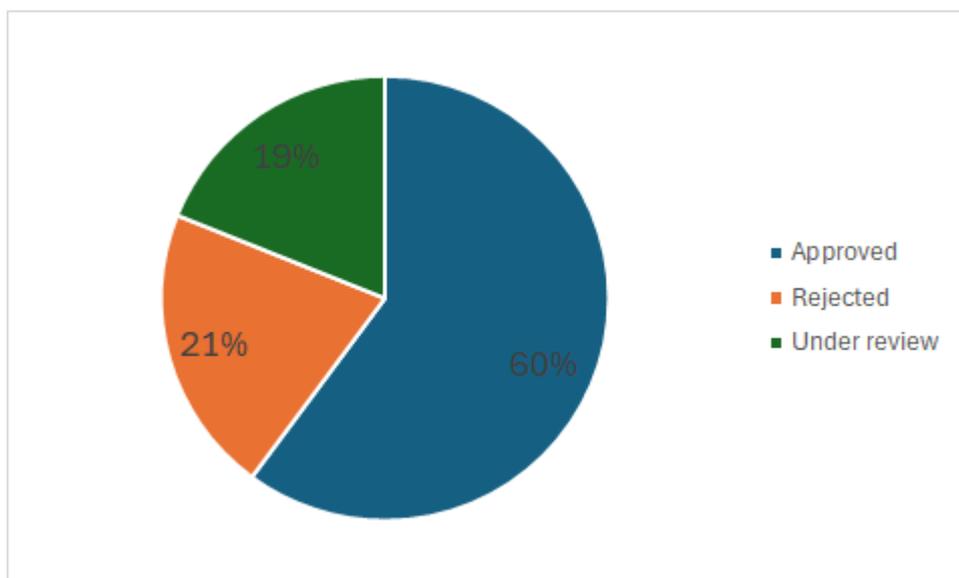


Figure 3. Proportions of Approval and Rejection under the Relief System for Injury to Health with Vaccination in 16 Wards of Tokyo

(Data: June 2025. Author’s calculations. The total number of approved, rejected, and cases under review is 587.)

For comparison purposes, we examine this ratio in relation to data from the Disease and Disability Certification Review Board (Shippei · Shougai Nintei Shinsakai) of the Ministry of Health, Labour and Welfare.<sup>4</sup> As of January 16, 2026, the number of forwarded and accepted cases was 14,728, of which 9,421 were approved and 4,395 were rejected, while 912 cases remained under review, corresponding to 6.2% of the total. Moreover, when the number of approved cases is calculated as a proportion of the combined total of approved and rejected cases, the approval rate is 68.2%.

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<sup>4</sup> See Results of Deliberations by the Subcommittee on Infectious Diseases and Immunization of the Disease and Disability Certification Review Board — First Panel on COVID-19 Vaccination Injury (Shippei Shogai Nintei Shinsakai Kansensho Yobosesshu Shinsa Bunkakai Shingata Korona Uirusu Kansensho Yobosesshu Kenko Higai Shinsa Dai-ichi Bukai Shingi Kekka) (Ministry of Health, Labour and Welfare).

We next conduct further analysis based on data obtained through public information disclosure requests concerning the Relief System for Injury to Health with Vaccination in the 23 wards of Tokyo. Among the disclosure requests submitted to the wards, several provided information on whether a Report on Suspected Adverse Reactions had been filed for each application under the relief system. For six wards, data were available on both the presence or absence of a Report on Suspected Adverse Reactions and the corresponding approval or rejection outcomes.

There were 39 applications for which a Report on Suspected Adverse Reactions had been filed, of which 36 were approved, yielding an approval rate of 92.3%. In contrast, there were 109 applications for which no such report had been filed, of which 74 were approved, corresponding to an approval rate of 67.9%. These figures may give rise to the interpretation that the absence of a Report on Suspected Adverse Reactions reduces the likelihood of approval under the relief system.

### **3. Information Disclosure on the Report on Suspected Adverse Reactions**

By examining the Report on Suspected Adverse Reactions, it is possible to understand the status of adverse reactions associated with vaccination. Such reports provide information on who received vaccinations and what kinds of symptoms were experienced, and thus can serve as important reference materials for individuals when considering vaccination. These materials can also be obtained through public information disclosure requests. However, the information obtainable from disclosure requests regarding adverse reaction reports varies across municipalities. In what follows, we provide an explanation based on materials submitted to an information disclosure review board in connection with a public information disclosure request made to a certain city.<sup>5</sup>

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<sup>5</sup> According to the Fukuoka City Information Disclosure Review Board (Joho Kokai Shinsakai), the Board functions as an impartial third-party body responsible for investigating and deliberating administrative appeals (Shinsa Seikyu) concerning information disclosure.

We conducted a survey across all 47 prefectures to examine the extent to which information contained in the Report on Suspected Adverse Reactions is disclosed. With respect to the “summary of symptoms,” our review of all 47 prefectures found that such information is disclosed in only six prefectures. In several of these prefectures, the “reporter’s comments” are also disclosed. However, in some prefectures, the adverse reaction report forms themselves are not disclosed; instead, authorities release lists of symptom names and related information compiled by administrative bodies based on the Report on Suspected Adverse Reactions. These findings indicate substantial inter-prefectural disparities in the disclosure of information from the Report on Suspected Adverse Reactions. It should be noted that the “summary of symptoms” provides a chronological account of the symptoms experienced after vaccination and their eventual outcomes, thereby enabling a detailed understanding of actual cases.

Itagaki (2024) states that “placing excessive emphasis on the protection of individual privacy at the expense of due consideration for citizens’ right to know is not appropriate.” From this perspective, further examination is warranted as to the extent to which non-disclosure of the “summary of symptoms” can be justified. At the same time, it is reasonable from a privacy standpoint that personal identifiers, such as individuals’ names and the names of hospitals where treatment was received, should be withheld from disclosure.

Moreover, Article 7 of the Act on Access to Information Held by Administrative Organs provides that “even when an administrative document subject to a disclosure request contains non-disclosable information (excluding the information listed in Article 5, item (i)-2), if the head of the administrative organ finds that disclosure is particularly necessary in the public interest, the administrative organ may disclose the relevant administrative document to the requester.”<sup>6</sup> In addition, Article 6 of the Act on Access to Information Held by Administrative Organs provides that “where a portion of an administrative document subject to a disclosure request contains non-disclosable information, and where the portion containing such information can be easily separated and removed, the head of the administrative organ shall disclose the remaining portions to the requester. However, this shall not apply if it is

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<sup>6</sup> See e-gov Horei Kensaku “The Act on Access to Information Held by Administrative Organs (Gyosei Kikan no Hoyu suru Joho no Kokai ni Kansuru Horitsu).”

recognized that no meaningful information is recorded in the remaining portions.” From this perspective, the question arises as to whether withholding the “summary of symptoms” in its entirety is consistent with this Act.

Furthermore, Takahashi, Saito, and Uemura (2023, p. 320) state as follows: “In determining mandatory disclosure in the public interest, the degree of likelihood that disclosure will bring about benefits should be assessed relative to the legal interests protected by such disclosure. In cases such as the present one, where disclosure may prevent death or serious health damage, it is not appropriate to require a high level of likelihood that such protection will be achieved.”

#### **4. Conclusion and Issues Concerning the Relief System for Injury to Health with Vaccination**

Although this paper has examined the Relief System for Injury to Health with Vaccination and the Report on Suspected Adverse Reactions, this section discusses additional issues that were not addressed in the previous sections.

Claims under the Relief System for Injury to Health with Vaccination related to emergency vaccinations and routine vaccinations for Category A diseases are not subject to any application deadline. However, there is an important issue to consider regarding the documents required to receive benefits under this system: namely, the possibility that applicants may be unable to gather the necessary materials at the time of application. Among the required documents is the medical record (clinical chart). With respect to medical records, Article 24 of the Medical Practitioners Act provides as follows.<sup>7</sup>

“(2) With respect to medical records referred to in the preceding paragraph that relate to medical treatment provided by physicians employed at hospitals or clinics, such records shall be retained by the administrator of the relevant hospital or clinic; with respect to records relating to other medical treatment, they shall be retained by the physician concerned. In either case, such records must be preserved for a period of five years.”

Although a five-year retention obligation is imposed, some hospitals are presumed to preserve medical records for periods exceeding five years; however, the actual situation

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<sup>7</sup> See e-gov Horei Kensaku ” Medical Practitioners Act (Ishiho).”

remains unclear. Professional ethical guidelines for physicians also indicate that long-term preservation is desirable.<sup>8</sup> Even though no time limit is imposed on filing claims, it is anticipated that applicants may be unable to submit applications due to difficulties in assembling the required documents, or may be forced to submit incomplete applications, which could place applicants at a disadvantage in the future.<sup>9</sup>

Finally, we also address cases in which applications to the Relief System for Injury to Health with Vaccination result in non-payment. In such cases, administrative appeals may be filed; however, this appeal process itself presents significant challenges. For example, Enoki (2025, p. 139) states that “the prefectural governor who receives an administrative appeal shall examine the matter, including the appropriateness of the causal determination made by the Minister of Health, Labour and Welfare,” while also noting that “it is not possible to file administrative appeals regarding the Minister of Health, Labour and Welfare’s determination of causality.” As a result, applicants cannot directly challenge the causal determination itself. In practice, disputes take the form of contesting the municipality’s decision of non-payment, to which municipalities repeatedly respond that “the non-payment decision was made based on the national government’s determination.” These exchanges are conducted not only through written submissions (the exchange of statements of explanation and rebuttals) but also through opportunities for oral statements, during which questions and answers may be presented.

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<sup>8</sup> See Japan Medical Association (2016).

<sup>9</sup> According to Pharmaceuticals and Medical Devices Agency (PMDA), “Handling of the Relief System for COVID-19 Vaccination (Shingata Korona Wakuchin Sesshu ni okeru Kyusai Seido no Toriatsukai ni suite),” individuals eligible for routine vaccination on or after April 1, 2024 are designated, and for those who fall under routine vaccination, applications are processed under the Relief System for Injury to Health with Vaccination as routine vaccination for Category B diseases. In addition, Ministry of Health, Labour and Welfare, “On the Relief System for Injury to Health with Vaccination,” stipulates with respect to Category B disease vaccinations that claims for medical expenses must be filed “within five years from the date on which payment of the relevant medical expenses was made,” indicating that a claim deadline applies.

Noguchi (2022, p. 180) also notes that “of the 57 individuals whose applications were rejected, five requested reconsideration, but all were again rejected.” Although this refers to the certification status of health injuries following the 2009 pandemic influenza vaccination, it illustrates the difficulty of overturning an initial rejection. Nevertheless, articles in *The Nikkei* indicate that there are cases in which decisions of non-payment are subsequently reversed.<sup>10</sup>

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<sup>10</sup> See Nikkei Inc. “27-nen Mae no Sesshu Higai o Kyusai e — Tochigi-ken, Fushikyū Torikeshi (2017/9/19 18:26)”

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