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Review of the Laws on the Dissemination of False Medical and Unreliable Health Information in Japan

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ABSTRACT

The purpose of this paper is to examine the regulation of dissemination of false medical and unreliable health information on social networking services in Japan. The paper provides an overview of the current status of false medical and unreliable health information in relation to Covid-19 and reviews how these are addressed by current legislation in Japan.

Keywords: Japan; Law; Japanese Law; Fake News; Medical Fake; Misinformation; Disinformation

Introduction

In light of the global COVID-19 pandemic, several research institutions and pharmaceutical companies in different countries conducted research toward bringing the pandemic to an end. Various national governments and public institutions disseminated measures and information on COVID-19 based on the stage of infection. In addition to this, Social Networking Sites (SNS), blogs, and websites played a prominent role in transmitting information during the pandemic. These non-public disseminators of information included posts by members of the general public who were unfamiliar with medical information, and apparently highly credible disseminators of information, such as experts, doctors and researchers, politicians, volunteer groups of doctors, and medical companies. Some of the information they provided were drawn from public information or based on medical findings. However, some information was unreliable and/or clearly false. For example, there were claims of the efficacy of medical and pharmaceutical products whose effectiveness had not been demonstrated, and harmful hoaxes against preventive measures such as vaccines. These issues existed even before the COVID-19 pandemic. However, with the development of SNS and the emergence of the COVID-19 pandemic, these issues spread on a global scale. There is also the danger that those who act on such false medical and unreliable health information will be harmed by the drugs they consume or the exacerbation of infectious diseases. This study examined the laws in force in Japan in relation to the dissemination of false medical and unreliable health information.

Current Status

False Medical and Unreliable Health Information

In this study, false medical information was defined as misinformation and disinformation concerning medicine, such as medical practices and medical and pharmaceutical products. Unreliable health information is defined as information on medical practices or medical and pharmaceutical products that is not necessarily misinformation or disinformation, but rather information that has been verified yet, in other words, information on medicine that is low in authenticity. The former includes information that is clearly false, and the latter includes information that later turns out to be true or false following research and clinical trials [1].

The following information related to COVID-19 is considered false medical information [2]:

a) Fifth Generation Mobile Communication System (5G) contributed to the spread of COVID-19.

b) The US Court of Appeals ordered a halt on the use of COVID-19 vaccines.

c) Steps were skipped in clinical trials of the COVID-19 vaccine.

d) COVID-19 vaccines lead to infertility.

These items are examples of the information that spread in Japan. They were fact-checked by government agencies and nongovernmental organizations and identified as misinformation. Item a) spread in the UK, and comprised information without any scientific basis, just like false information that nanoparticles were mixed into COVID-19 vaccines, despite the UK government denying this causal relationship [3]. For b), there was no evidence that the US Court of Appeals issued such an order [4]. For c), the clinical trials in the approval process went through Phase I (clinical pharmacology), II (exploratory), and III (confirmatory) trials, leading to human administration. This process is the normal clinical trial process [5]. Government agencies also declared item c) misinformation [6]. For d), some of posts were reposted on SNS and spread worldwide. Infertility caused by vaccines had already been ruled out after verification of whether or not there was an increase in the miscarriage rates among pregnant women after vaccination, although each country has been forced to take measures such as publicity activities to spread awareness on accurate information. In Canada, there were posts on SNS saying that impacts of the COVID-19 vaccine on reproductive function were recorded in Ontario, and some legislators were involved in spreading such information. Ontario published a list of births from 2020 to 2021, officially denying any link between COVID-19 vaccines and infertility [7].

Examples of unreliable health information are as follows:

a) Effectiveness of masks on preventing infection.

b) Effectiveness of vaccines in preventing infection.

c) Effectiveness of specific health foods and supplements on COVID-19.

d) Effectiveness of specific medical and pharmaceutical products on COVID-19.

Some of this unreliable information have been sites of academic conflict. Although there are some negative views on e) and f), they are generally accepted as effective, and considered effective according to regular medical findings [8]. There have been scattered cases in which the effectiveness of g) and h) were confirmed at the test tube level (in vitro) despite not clearing subsequent clinical trials or studies, and cases of sporadic effectiveness in the research process. For g), green tea and other substances were studied in Japan. For h), there was a problem concerning the indication of existing drugs such as hydroxychloroquine and ivermectin for COVID-19. Ivermectin has been reported as a health hazard if taken mistakenly [9]. The US House of Representatives Special Subcommittee on the Coronavirus Crisis conducted an "investigation of (specific) online businesses promoting access to unproven and dangerous coronavirus treatments such as hydroxychloroquine and ivermectin" in October 2021, the purpose of which was to prevent any profiting from jeopardizing the lives of Americans, hindering measures to prevent infectious disease, and spreading misinformation, by spreading improper remedies [10]. False medical and unreliable health information like that described above risks dissuading people who come in contact with such information from seeking proper medical treatment or hindering proper infectious disease prevention measures, which may imperil their lives or physical well-being. Thus, measures are needed to combat such harmful medical misinformation.

Current Measures

At the time of writing, there were no laws directly regulating false and unreliable information in Japan. Of course, this is not to say that there are no restrictions at all on the dissemination of this information. If such information touches on other legal norms, for example, they may fall under Article 230 of the Penal Code for defamation [11] or under Article 233 of the Penal Code for fraudulent obstruction of business [12]. However, with the growth of the internet and emergence of SNS, the risks of spreading false and unreliable information are now increasing. In addition to the false and unreliable information related to medicine dealt with in this paper, there is also the danger that intentionally disseminated disinformation will interfere with the operation of nations, electoral systems, and corporations. Deepfake images and videos produced and synthesized using Artificial Intelligence (AI) present false information as though it were true [13]. Under these circumstances, the need for regulating highly dangerous false and unreliable information is being discussed. In Japan, as in the case of Canada, the dissemination of correct information is mainly. However, the freedom of expression under Article 21 of the Constitution applies to information dissemination via SNS, and thus, in principle, it is free from government interference.

Freedom of expression is one of the foundations for the freedom of thought, and is protected except in exceptional cases that are contrary to public welfare or that harm the rights and freedoms of others. Rather than legally regulating disseminators of false information, regulating the platforms offering venues for the dissemination of such information is being considered. For example [14] in Germany and France, [15] legislation has made it mandatory for platformers to delete false information. However, these regulatory laws have been criticized over doubts about their effectiveness and the risk of overly blocking the freedom of expression [16]. At the time of writing, Japan had not made it mandatory for platformers to delete fake news. A study on platform services of the Ministry of Internal Affairs and Communications indicated a possible direction for future research [17]. The government respects the voluntary

efforts of private business operators and monitors their efforts, and exercises caution while intervening. However, it is also suggested that the government will intervene to some extent if private sector efforts are not successful or are not expected to have an effect. A code of conduct would be formulated for platform operators, who would report and publicize the status of measures for ensuring transparency and accountability [18]. However, at the time of writing, platformers and other private business operators were not directly regulated, and government intervention aimed to respectfully supplement the voluntary efforts of the private sector.

To prevent the spread of false and unreliable information, careful measures that do not unduly restrict the freedom of expression must be taken. However, some level of response is demanded in order to prevent the infringement of the legal interests of society and individuals resulting from such information. False medical and unreliable health information risks damaging the health of recipients of such information, and the spread of infectious disease infringes on social and legal interests such as public health, and endangers legal interests such as the lives and well-being of individuals. A survey of individuals aged between 20 and 49 years in Japan showed that 71% of people encountered rumors related to COVID-19, 5% believed them, and 42% were skeptical. The survey also suggested that information cancelling out rumors by fact-checking was not sufficiently disseminated [19]. Even false or unreliable information sometimes does not infringe on legal interests. Unreliable information may be carefully deleted in the course of free research and development, such as while publicizing the research itself. Deleting this information indiscriminately even after platformers and other private operators have taken voluntary measures can lead to excessive blocking of information. Deleting posts without a legal basis risks legal problems for platform operators and other businesses. Therefore, some legal basis should be found in deleting false information despite voluntary private efforts. The next section identifies the regulatory scope of current laws for false medical and unreliable health information.

Responding with Current Laws

Consumer Protection: Act Against Unjustifiable Premiums and Misleading Representations (AAUPAMP)

Article 1 of AAUPAMP states that it is "for the purpose of protecting the interests of general consumers by stipulating limitations and prohibitions on acts that may hinder voluntary and rational choices by general consumers, in order to prevent customers from being enticed by unjustifiable premiums and representations related to the transaction in goods and services," and may address false medical and unreliable health information from the perspective of consumer protection. Article 5 concerns the "prohibition of misleading representations," and regulates unjustifiably enticing customers or hindering voluntary and rational choices by general consumers through "representations indicating to general consumers that, contrary to the facts, the quality, specifications or other content of goods or services are significantly superior to the actual product, or to those of other business operators supplying the same or similar goods or services" (Item 1). In Article 5, Item 1 of AAUPAMP, when there is a concern for "misrepresentation of good quality," pursuant to Article 7, Paragraph 2, "Business operators who have made such representations may be requested to submit materials showing reasonable grounds to support such representations within a specified period of time," and may be subject to regulations for unproven advertising if they cannot submit materials satisfying the following criteria:

1) Submitted materials have objectively verified content

2) There is appropriate correspondence between represented effects and performance, and the content is verified by submitted materials.

The first criterion means that the results are obtained by tests and investigations according to generally accepted methods or methods recognized by experts in related fields, and if there are none, then methods, etc., recognized as appropriate under socially accepted norms or according to the opinions of experts, expert associations, or professional bodies, or scholarly literature in generally recognized related fields. The second criterion means that in addition to submitted materials themselves having objectively verified content, the represented effects and performance appropriately correspond to the content verified by the submitted materials. An example of a product that does not meet the above requirements and falls under Article 5, Item 1 is a recent case in which the labeling of a so-called space disinfectant claimed to remove bacteria in the air and was misidentified as being a superior product [20]. Some products have claimed to have weight reduction effects but its effects were not proven [21]. Misleading advertisements may fall under the category of "encouragement by a business operator to conclude a consumer contract" under the Consumer Contract Act (Articles 4 and 12, Paragraph 1) [22]. The Act on Specified Commercial Transactions stipulates regulations on misleading advertisements, calling them "Representations significantly different from the facts, or that mislead people into thinking that something is significantly better or more advantageous than the actual product'" (Article 12).

Act on Securing Quality, Efficacy, and Safety of Products Including Pharmaceuticals and Medical Devices (Pharmaceutical and Medical Devices Law)

The Pharmaceutical and Medical Devices Law states that its "purpose is to ensure the quality, effectiveness, and safety of medical and pharmaceutical products, quasi-pharmaceutical products, cosmetics, medical devices, and regenerative medical products (hereinafter, "medical and pharmaceutical products, etc."), and provide necessary regulation to prevent the occurrence and spread of hygiene hazards stemming from the use thereof, and in addition

to taking measures to regulate scheduled drugs, take necessary measures to promote research and development of medical and pharmaceutical products, medical devices, and regenerative medical products particularly needed in medicine, and thus improve hygiene, and provide multiple advertising regulations from the point of view of hygiene." Article 66 (Deceptive advertising, etc.) states that "false or exaggerated articles about the names, manufacturing methods, efficacy, effects, or performance of medical and pharmaceutical products, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medical products, whether express or implied" (Paragraph 1), and "advertisements that may be misunderstood as articles endorsed by doctors or other persons on the efficacy, effects or performance of medical and pharmaceutical products, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medical products" (Paragraph 2) are subject to regulation. Paragraph 1 defines an actor as "anyone," and includes people other than "doctors and others," so even posts by SNS users who do not have medical knowledge may be subject to the law.

Paragraph 2 refers to "doctors and others," that is, "doctors, dentists, pharmacists and others who have a substantial influence on the public perception of the efficacy, effects or performance of medical and pharmaceutical products, etc.," [23] and regulates advertising by those who can provide professional endorsements. Advertisements are defined as anything meeting the requirements of "having a clear intention to attract customers (increasing customer willingness to purchase)" and "having a clear product name, such as specific medical and pharmaceutical products," and "being recognizable to the general public" (three requirements of advertisements) [24]. Article 68 prohibits advertising the names, manufacturing methods, efficacy, effects, or performance of pre-approved medical and pharmaceutical products, medical devices, and regenerative medical products. Posting advertisements on SNS about health foods whose effects have not been objectively verified, such as effects on COVID-19, or medical and pharmaceutical products that have not been approved in Japan, are subject to regulation under Articles 66 and 68.

Pre-approved medical and pharmaceutical products are subject to Article 68 even if they are approved for other indications, as off-label advertisement as a medical or pharmaceutical product is prohibited as long as partial change approval under Article 14, Paragraph 15 has not been obtained [25]. In Japan, personal importing of medical and pharmaceutical products is not prohibited. However, if such products are not domestically approved, they may be subject to Article 68 if information is disseminated such that the importing agent of those products meets the three requirements of advertisements mentioned above. For example, if a medical and pharmaceutical product such as ivermectin, which is currently not indicated for COVID-19, is advertised as a medical and pharmaceutical product indicated for COVID-19, it may fall under this article. Even though food products are generally not considered medical and pharmaceutical products, if a claim is made of them having efficacy, effects, or performance against diseases, then they shall be considered unapproved medical and pharmaceutical products [26]. Recently, there was an arrest under Article 68 for the posting of advertisements claiming that health foods had effects on COVID-19 [27]. Article 6-5 of the Medical Care Act prohibits false advertising, including deceptive advertising (Paragraph 2, Item 2), and regulates the advertising of medical practices not subject to the Pharmaceutical and Medical Devices Law, whereas Article 65 of the Food Promotion Act prohibits representations of the health preservation and enhancement effects of "products offered for sale as food" that are significantly inconsistent with facts and are grossly misleading.

Such representation and advertising regulations concerning consumer protection are not in an exclusive relationship with the hygiene and public health advertising regulations mentioned here. As for advertisements related to specific products, some cases fall under mislabeling under AAUPAMP and the advertising regulations of the Pharmaceutical and Medical Devices Law, whereas others do mislabel under AAUPAMP and fall under deceptive advertising under the Health Promotion Act.

Medical Ethics: Medical Practitioners Act

The Medical Practitioners Act stipulates under Article 1 that the role of doctors is to "contribute to the improvement and enhancement of public health by administering medicine and health guidance, thus ensuring a healthy life for the people," and sets forth norms for doctors to uphold. Under this law, no article regulates the posting of false and unreliable health information by doctors through advertising. The problem here is whether the act of disseminating medically false or unreliable health information in future should be included among the acts covered by Article 7 of the law, namely "acts that damage the respectability as a medical practitioner," which result in administrative action. "Acts that damage the respectability as a medical practitioner" refers to "acts that do not fall under any of the items of Article 4 (of the law) and that damage the respectability as a medical practitioner," and are determined on a case-by-case basis. In a recent case, an administrative penalty was imposed in 1982 for abandoning the treatment of a large number of hospitalized patients, but no clear definition of "acts that damage the respectability as a medical practitioner" is provided [28]. Article 7 applies to cases where there is a high risk to the life or physical well-being of the patient, such as refusal of medical treatment, [29] and does not envisage the dissemination of dissemination of false or unreliable information by doctors. Disseminating inaccurate information during a pandemic may jeopardize public health and individual life, well-being, and legal interests. If the impact of the dissemination of such information is considered in the light of the danger it poses to society, it is not less permissible. Careful consideration must be given to whether or not to include these acts of disseminating information with "acts that damage the respectability as a medical practitioner."

In California, Assembly Bill No. 2098 (AB2098) has recently been enacted as a revised bill adding Section 2270 to the California Business and Professions Code. This considers misinformation leading patients to avoid vaccination to be a problem in light of the magnitude of damage caused by COVID-19, and explicitly regulates the dissemination of medically false and unreliable information by doctors [30]. The dissemination of mistaken or false information on COVID-19 is considered unprofessional conduct and can result in the suspension of a doctor's license. However, from the perspective of the freedom of expression and medical practice, [31] this provision has been strongly criticized as excessively blocking the dissemination of information, and multiple lawsuits have been filed [32]. At the time of writing, all lawsuits maintained the reasonableness of AB2098, but close attention must be paid to future developments.

Limits of Regulations on Information Dissemination and Freedom of Research

Personal Opinion on the Scope of Regulations on Expression

Disseminating false medical and unreliable health information includes the risk of jeopardizing public health and the lives and well-being of individuals. However, to prevent the unfair infringement of the freedom of expression by excessive blocking despite private voluntary regulation, careful consideration must prevail, including limiting the scope of regulation to dissemination of information with high penalties. In light of the advertising and representation regulations under the current laws, this means posts carrying risks to consumers, hygiene, and health, that is, information in posts with no objective evidence based on general findings in specialized fields, and that may draw a reader into a dangerous situation. Information such as this found on influential SNS accounts of doctors may lend more credibility to false medical and unreliable health information, and deserve greater punishment. Even if information in a post is low in objective evidence based on general findings in a specialized field, for example, information based on papers that have not been peer reviewed, if they do not lead readers to unapproved drugs, food, or medical practices with no proven effects, the risks of the information endangering readers is low, as should be the punishments. However, if information is low in putative value, but may still discourage proper medical practices, some method other than deletion, though not legal intervention, may be preferable.

This may include enhancing systems to facilitate access to information for fact-checking or countering false information. Excluding all information with low objective evidence based on general knowledge in a specialized field from information markets hinders free research and development. Problems may arise if the government's public information is later found to be erroneous, which can change current general knowledge. Transparency must be ensured in medical research in order to respond to cases in which currently recommended medical and pharmaceutical products cause drug-related injuries [33].

Limits of Advertising Regulations

The dividing line between highly punishable information that should and should not be deleted even if it is unreliable health information, is whether information draws readers into a dangerous situation. Does it fit the advertising requirement of "having a clear intention to attract customers (increasing customer willingness to purchase)?" Here, the Supreme Court decision in the Diovan case serves as a reference [34]. On whether an academic paper could be counted as advertising under Article 66, Paragraph 1, the Supreme Court cited the Pharmaceutical and Medical Devices Law, which says that, "It is appropriate to understand the act of 'advertising, describing or distributing an article' in relation to specific medical and pharmaceutical products as notifying an unspecified number or many people of the matters prescribed in the same paragraph, as a means of encouraging the purchase or prescription of those medical and pharmaceutical products," and on the basis of it being "Appropriate to objectively determine whether or not a notification can be said to have been made as a means to encourage the purchase or prescription of specific medical and pharmaceutical products regulated under the same paragraph, referring to the content, nature, and mode of the notification," ruled out the eligibility of the academic paper as advertising. This decision considers the nature of academic papers, which are subject to criticism and debate by other academic experts. The supplementary opinion mentions the danger of restricting the creation, posting, and publication of academic papers under Article 66, Paragraph 1, as having a chilling effect on the freedom of expression.

Naturally, this decision is about an academic paper, and posting to a general SNS is not assumed. However, in the light of the intent of this decision, if the content of a post can be objectively determined to not draw a reader in as a means to encourage the purchase or prescribe of medical and pharmaceutical products, namely, clearly state only information on a research process and serve as public relations for research, then even if it disseminates unreliable information, it should probably remain unrestricted [35-40].

Conclusion

We have discussed how current laws in Japan are addressing medically false and unreliable health information. Legal discussions on expanding the scope of regulation for such harmful information have not progressed much beyond legal theories. Under the current laws, they can only be dealt with through self-regulation by platformers and the regulation of advertising and representation under some laws. This paper offered explanations and a few personal opinions. This article only introduces Japanese law because of the subject matter, but political and legal responses to false medical and unreliable health information can also be found in other countries,

such as Ontario's response in Canada and California's AB 2098. This point will be discussed in the next and subsequent articles.

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