

Japan

Special Report

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INTERNATIONAL
CAMPAIGN
FOR WOMEN'S
RIGHT TO SAFE
ABORTION

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Special Report on Japan's approval in 2023 of abortion pills : three reports



Marion Ulmann presenting medical abortion products and the international experience to the investigators of the Japanese Phase 3 trials

Tokyo, June 2019

1. Japan's crawl towards medical abortion: Why was Japan the last of the G8 countries to approve mifepristone?

by Marion Ulmann

One of the world's most common regimens for terminating a pregnancy medically involves taking a combination of two medicines, one called mifepristone (which blocks progesterone, a hormone necessary to continue a pregnancy) and the other called misoprostol (which induces uterine contractions).¹

Mifepristone is a synthetic steroid that was discovered in France in 1980.² By 1985, China had begun clinical trials on the medication, and within three years, became the first country in the world to approve use of mifepristone for medical abortions.³ France followed a few short weeks later.⁴ The United States granted approval in 2000, Australia in 2012, and Canada in 2015.

In fact, by the end of 2022, 93 countries had approved mifepristone with misoprostol for use in terminating a pregnancy.⁵

Not until April 2023, however, did a panel from Japan's Health Ministry approve the two-drug regimen, making the combination of mifepristone and misoprostol legal for medical abortion.⁶

The question for this article is straightforward: Why is that, despite having the world's third-largest economy, standing among the world's largest producers of motor vehicles, electronic equipment, and steel, and being among the most literate countries in the world,⁷ is Japan so far behind its peers on reproductive rights?

I – Registration of medical abortion

Japanese culture posits a decidedly different view of sexual and reproductive health from its G8 counterparts, a driving factor in explaining the delays in approval.⁸

The World Economic Forum's Global Gender Gap Report ranked Japan 116th, near Burkina Faso and Tajikistan,⁹ and indeed, the country's cultural mores can be seen clearly in its abortion laws: Japan is one of just 11 countries that requires spousal consent for abortions, and women must consult with doctors to get oral contraceptives.¹⁰

A brief review of the country's demographics helps explain the persistence of these laws and norms. The country's political positions have long been dominated by men,¹¹ and today less than one quarter of all doctors in the country are women, according to the Health Ministry.¹²

The result is that Japanese women have had relatively few formal avenues to advance change.

Thus, despite approving emergency contraceptive in 2011, and birth control pills in 1999 (also nearly four decades after much of Europe and the West), available abortion procedures have predictably remained woefully archaic.¹³

According to a recent CNN article, the Japanese public broadcaster NHK noted that prior to April 2023 when the pill was approved, only surgical abortion was available in Japan through two methods: the *"curettage method, which scrapes out the tissue inside the uterus with a metal instrument, and the aspiration method, which sucks out the tissue through a tube."*¹⁴ WHO approves and recommends the aspiration method as an outpatient procedure, but curettage was labelled long ago by the World Health Organization (WHO) as *"obsolete"*. They have called for it to be replaced by the aspiration method or the abortion pills mifepristone & misoprostol.¹⁵

Another contributing factor is the fact that the Pharmaceutical and Medical Devices Agency (PMDA), the Japanese equivalent of the US Food and Drug Administration (FDA), ordered that the development of the

drug begin from scratch, eschewing the available international data supporting adoptions of the medical abortion regimen.

I met with the PMDA in 2013, and only then did Japan launch the decades-long pharmaceutical development process, conducting 12 clinical trials (more than any other country) for an average of five years each, and holding a specific Phase 3 trial focused on Japanese women.

For comparison, other countries began and completed the process in just two years, a fraction of the time.

II – Public support

So how did adoption ultimately happen? In addition to simultaneous pharmaceutical and clinical developments, advocacy and local support groups played a major role in pushing the country forward, with Japanese women and doctors leading the charge.

In my first meeting with the PMDA, the country's leaders didn't see the pressing need for medical abortion, arguing that the available surgical methods were sufficient. And indeed the obstetricians and gynaecologists we met with in 2010 expressed similar ambivalence, content with the available surgical options.

Undeterred, our team focused on making clear the importance of patient well-being, while also making explicit the clear practical benefits: patient discretion, procedural speed and efficacy, and economic prudence.

Japanese women, we argued, deserved to have the right to choose the option of taking two types of pills instead of the arduous and emotionally and physically dangerous and debilitating curettage method.

In time, the argument began to sink in and large-scale social efforts across the country started bearing fruit.

In 2016, for example, I organised a conference that registered only a dozen attendees. Our most recent convening, however, welcomed over 100 of the country's doctors.

Indeed, my Japanese colleagues and our team have worked diligently for a decade to train hundreds of doctors about the benefits of medical abortion, and increasingly, our attendees demonstrated receptivity to global data that supports the compelling case for the benefits of medical abortion.

Evidence of a social evolution was also obvious on a national scale: prior to the approval for medical abortion, the Minister of Health (MHLW) received more than 12,000 comments regarding the product, with the number of opinions in favour of adoption **double** the number of those opposed.

III- Future of medical abortion in Japan

Despite the tremendous success of grassroots movement in pushing through the approval, there remain immense obstacles for Japanese women.

The requirement for spousal approval noted above is an obvious hindrance, but there are also additional roadblocks. For instance, according to Bloomberg, access to the two-pill regimen will remain limited to hospitals and the medications will not be covered by insurance, making them prohibitively expensive for many.¹⁶ Per Bloomberg: *“While the price hasn’t been disclosed yet, the Mefeego pack is estimated to be around ¥50,000 (\$354). That’ll make the full procedure — from tests to the drug and hospitalization — cost about ¥100,000, only a little less than surgery, according to the Japan Association of Obstetrics and Gynecologists.”*¹⁷

Today, Italy is the only other country in the world that demands patients be hospitalised when taking the misoprostol pills, and if, as noted above, the benefits of medical abortion include, among other things, speed, efficiency, and discretion, then key advantages are eliminated by the onerous requirement of hospitalisation.

There is also little evidence to justify hospitalisation: medical abortion results in menstrual bleeding similar to any woman’s normal menstrual cycle. Unpleasant, but entirely familiar. Bluntly put, requiring that patients be admitted appears to be an attempt by conservative Japanese doctors and politicians to make the process more complicated and expensive than it needs to be.¹⁸

Further evidence of this claim is that the PMDA has placed severe restrictions on the centres permitted to dispense the medical abortion regimen. These facilities must be certified and have the requisite amenities required for in-patient hospitalisation.

Consequently, less than 1% of all medical facilities have received the required approval.

In contrast to the United States or Canada or the United Kingdom, where medical abortion pills can be prescribed via telemedicine, or in Australia and Canada where the medications are available in pharmacies, Japan exemplifies a country crawling towards progress.

Indeed, while my colleagues and I are working globally on the next frontier of bringing medical abortion to “over-the-counter status”, in Japan this remains an unrealistic short-term goal. But the Japanese population has proven determined, and with support from the international community, our hope is that progress for Japanese women is still very much in sight.

About the author:

Marion Ulmann was the General Manager of Linepharma International and Board member of Linepharma KK, Japan. She oversaw the development and registration of medical abortion in Japan. She has been instrumental in registering medical abortion pills in more than 20 countries around the world (including Canada, Australia and in Latin America).

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2. What my Yahoo Japan! articles revealed about the long-delayed approval of abortion pills in Japan

by Masako Furukawa

Japanese journalist Masako Furukawa wrote an extensive investigative report based on interviews with 28 stakeholders, using evidence from official documents and other sources, which was published in three parts in the Japanese Yahoo! News on 28-30 July. Here, she describes the interviews and research she conducted to prepare her report.

My report answers the question: "Why was the introduction of abortion pills in Japan delayed for 35 years?" I discovered many problems, in particular, how the Japanese Association of Obstetricians & Gynecologists (JAOG), was involved in causing this extensive delay.

I initially had no idea where the reason for the 35-year delay lay. Therefore, I conducted interviews with a wide range of people: pharmaceutical companies, obstetricians and gynaecologists in the field, executives of JAOG, politicians, bureaucrats, academics familiar with SRHR policy, and women who had campaigned for approval for the pills.

It took me four months to explore and find evidence to support a clear answer to this apparently simple question. I started the investigation in March of this year, one month before the Japanese Ministry of Health, Labour and Welfare (MHLW) approved the abortion pills, with the brand name Mefeego Pack, containing mifepristone and misoprostol. This event marked a step forward in Japan's reproductive health policy, at last. However, this combination of pills has been approved in more than 93 countries and territories since its approval in France in 1988. Why such late approval?

What has been reported up to this point was not sufficient to know the answer to this question. Some people mentioned the influence of doctors' organisations, religious forces and politicians, but when I interviewed them in detail, I realised that there was a lot of gossip and predictions. I therefore concentrated on finding evidence to answer this question. My Yahoo reports revealed circumstances that are unique to Japan, mainly in relation to the following three points:

(1) For many years, dilatation & curettage (D&C) has been widely practised in Japan as the main abortion method, blocking the way to using newer options for safe abortion. This arises from the fact that Japanese society has long been lacking in consideration for women's health, arising from the structure of male domination of both healthcare and politics.

(2) Those familiar with abortion in Japan believed that the JAOG, which is the organisation responsible for abortion in Japan, was responsible for the delay in introducing abortion pills. JAOG's executives have long been aware of the existence of abortion pills but have remained reluctant to introduce them. From the documents I found and the testimonies of senior members of this organisation who I talked to, it became clear that they had indeed long supported a policy of restricting access to abortion pills, even after Japan had approved Mefeego Pack.

(3) In 2012, Japan was advised by the World Health Organization (WHO) that they should not continue using the less safe curettage methods but should shift to other, safer methods. This has been previously reported. Newly this time, I reported that a person at the centre of JAOG had admitted that he had a negative view of the human rights issues identified by WHO and was reluctant to accept their recommendations.

I also interviewed a number of pharmaceutical professionals, from whom it became clear that in Japan, there has been little social understanding of medicines for women and that the pharmaceutical companies themselves faced difficulties in setting up clinical trials.

I learned that pharmaceutical companies that considered doing clinical trials had applied for approval at least twice before it was given, and there were companies and individuals who had considered the possibility of bringing the pill to market in Japan.

In 1989, the pharma company Japan Roussel (now Sanofi) considered providing mifepristone in Japan. However, a former employee of this company said that "social factors", including a campaign against abortion, had put a stop to the plan. Furthermore, around 2010, Dr André Ullmann, one of the developers of mifepristone, had contacted Japanese doctors to explore the possibility of introducing the abortion pill. However, due to a lack of interest from Japanese pharmaceutical companies as well as from obstetricians and gynaecologists, this did not take place at the time.

Eventually, development began in 2014, when Dr Ullmann's UK-based Linepharma headquarters commissioned two Japanese pharmaceutical companies to develop the pill package. But it was not until

2018 that a group of Japanese obstetricians and gynaecologists assigned a staff of doctors to be in charge of the clinical trial. Isamu Ishiwata, who is now the president of JAOG, admitted that they had not paid attention to introducing abortion pills for a long period of time.

“The fact that we did not encourage the pharmaceutical companies to introduce the method may also have had an impact.”

What became increasingly clear to me through historical review and interviews with senior executives of JAOG, was that they firmly believed that surgical abortion procedures, including curettage, are safe. Dr Ishiwata repeatedly emphasised how safe their methods of curettage and aspiration, with aspiration also sometimes including some curettage.

“From the very beginning, Japanese doctors have performed surgical abortion methods so safely that they are world-class,” he said. “As recognised in Japan's Maternal Protection Law, abortion is performed to protect motherhood and health. In Japan, our surgical methods are the safest in the world without the use of pills.”

On the other hand, Dr Ishiwata did not mention any psychological aspects of how women undergoing curettage or aspiration perceived the procedures, compared to abortion pills. I learned, however, that in the UK there have been surveys of how women themselves feel about the abortion methods available. I also learned that in Sweden, women who have chosen medical abortion have been surveyed about how they felt after using it. In both countries, the mostly very positive results have been published.

Dr Ishiwata's answers made me wonder why JAOG did not appear to be interested in the wishes of women. So, I decided to ask not only the chairperson but also the vice-chairperson, Dr Tsugio Maeda, who told me about the circumstances that make it difficult for women's views to be reflected in the abortion pill policy. He said:

“When we discussed our views on early abortion pills inside our organisation in 2013, there was only one woman in the group who we discussed it with.”

I feel that this lack of consideration for women's wishes and views in an ob/gyn association is closely linked to other gender gap issues existing in Japan. Despite the approval, the environment for abortion in Japan has not improved. Even after the introduction of the abortion pills, various developments have emerged that have hindered access to their use.

In practice, Mefeego Pack began to be used in May 2023, but even at the end of July, there were only 30 or so medical facilities in the country that were providing them. When a very small number of doctors took the initiative and started offering the pills, their colleagues called the health authorities and requested that detailed checks be put in place. It seems that their peers would monitor doctors who provided abortion pills. If such obstructive behaviour, which makes it difficult to provide medical care, continues, doctors in the field may become reluctant to introduce or continue offering the pills.

As my interviews continued, it became clear that JAOG's intentions continued to reflect efforts to restrict the use of the Mefeego Pack even after approval.

A statement by a JAOG executive suggested that he had heard that the strict conditions of use of the abortion pills were "heavily influenced by conservative politicians".

This suggested the involvement of politicians in making the restrictive policy but also suggested that JAOG was aware of the political developments, i.e. that they were "close to the politics". I therefore began to focus my research on the relationship between JAOG and politicians.

While looking through JAOG's documents, I found a "business report", which records the activities of the association's officers. I examined those from 2012, before the Phase 1 trials of the pills were launched, up to the present time. I found there were some close links with certain politicians. I drew attention to the behaviour of JAOG's senior management in 2021, at the time when Linepharma completed Phase III trials. At the same time as abortion pills were being discussed in the Parliament, a Parliamentary group on obstetric care had been established among parliamentarians. Executives of JAOG were at the same time also negotiating with the department in charge of abortion pills at the Ministry of Health, Labour and Welfare, and were also actively interacting with politicians. The politicians who had been appointed to the parliamentary group were those belonging to a conservative faction. I therefore also looked at the political funding bodies of the MPs who had joined the parliamentary group. I extended my research to their income and expenditure reports, and discovered that large donations had been paid by JAOG to those MPs. In the same year, the total amount paid to several Conservative MPs was more than three million yen (\pm US\$ 27,272).

Did the politicians return the favour to JAOG?

These questions led me to interview a Conservative politician who had received donations, a member of the House of Representatives, who denied any connection, saying that the donations had nothing to do with the abortion pill policy, as the parliamentary group was established for a different purpose. He also said that he had not interfered in the approval of the pills.

Meanwhile, the post-approval management system for abortion pills was discussed in the Liberal Democratic Party's Health and Labour Sub-Committee. I was told:

"It was pointed out within the Liberal Democratic Party that the operation of post-approval abortion pills should be tightened."

Another member of the House of Representatives was also interviewed. He is the chairman of the House of Representatives Health and Labour Committee. He acknowledged that the post-approval regulation of the pills reflected the wishes of some members of the House:

“The rule that the pills could only be used on an inpatient basis in a facility with inpatient beds was decided in the following way: Initially, many Liberal Democratic MPs were of the strict opinion that the use of the pills should be conditional on everyone using them to be admitted to hospital. The MPs eventually agreed to relax the conditions “a little”. He also said: “I am not particularly knowledgeable about obstetrics policy. It was JAOG who provided this specific advice when considering the use of oral abortion pills.”

When did JAOG seek to tighten the strict provision of the pills? To find out, I re-read the project report and found that a "Request for the oral abortion pill RU 486" had been submitted to the responsible section of the Ministry of Health, Labour and Welfare on 25 September 2013. That is where the strict operational requirements for the abortion pills, as desired by JAOG, were first stated. Also stated were concerns about the impact of the pills on the profitability of departments of obstetrics and gynaecology, all of whom charge women privately for abortions.

I therefore requested an interview with the person who submitted this request, Dr Katsuyuki Kinoshita, who was president of JAOG until last spring. After several rounds of negotiations, the interview took place in mid-June. When I asked about the reason for the 35-year delay, Kinoshita replied:

“We knew about the pills early on, but we didn’t think it was necessary to introduce them to Japan. Some doctors in the field said: ‘We are performing curettage and aspiration safely. We don’t need to introduce the pills.’”

I also told Kinoshita that some women do not wish to have surgery such as curettage and that the WHO has recommended medical abortion pills as being much safer. However, he replied:

“The WHO says that the pills are safer. But in Japan, I don’t think we need to follow it; the WHO is doing things mainly to deal with people in developing countries.”

This is of course not true. He also acknowledged that the wishes of JAOG were also reflected in the decision to limit the provision of abortion pills to medical institutions with in-patient beds. Ultimately, Kinoshita's comments suggested that JAOG was complicit in the long-standing delay in the introduction of the pills.

In Par 3 of my Yahoo article, I raised the issue of legislation. The reason behind the delay in introducing abortion pills was the influence of the old penal code, experts on the abortion issue said, which “criminalises abortion” and makes abortion a “crime carried out by women”. In Japan, whenever there is a report of an unassisted childbirth, the woman is always blamed. One of the women pointed out that this is because, at its roots, Japan is still a country with an “abortion law”.

Based on my findings, I am convinced that reluctance on the part of doctors is what is holding back the wider introduction and use of abortion pills.

Furthermore, I believe the media have been lax in their pursuit of attention to the case so far. While reporters, including those covering political and social sectors, show interest in certain subjects and scoops, no one seems to pay much attention to sins of omission, i.e. failing to do what should have been done to improve the quality of women's reproductive health care. As a result, the responsibilities of doctors' organisations and conservative politicians were also rarely pursued by the media in detail.

Male domination of health care, politics and media in Japan has maintained a significant lack of attention to women and women's health. This is both a structural problem and a problem involving strong prejudice and political power. Women's reproductive health needs more attention. Recently, when I covered a press conference held at the Ministry of Health, Labour and Welfare, by a women's organisation that is organising an action to expand the provision of oral contraceptives, there was only one male journalist among the media present.

Through my research, I was reminded of the need for journalists, both men and women, to continue to make visible the root of the problems surrounding women's reproductive health issues, including the sins of omission on the part of those in power.

About the author:

Masako Furukawa is a journalist who graduated from Sophia University in Japan. She has written non-fiction articles about the lives of celebrities for the weekly magazine AERA's "Portrait of Today" series. She is also the author of "Cancer Patient Studies of Awareness" (NHK Publishing Shinsho) and other works.

The original text of her three reports in Yahoo Japan (which are in Japanese only):

PART 1: "The long road to abortion pill introduction and barriers after approval"

<https://news.yahoo.co.jp/articles/e5688b69db3b3837d043b907f75a081d830f668f>

PART 2: "Why medical associations have remained reluctant to introduce abortion pills"

<https://news.yahoo.co.jp/articles/85663708926d02e4ea66ac43d016ed3d5e077f59>

PART 3: "Review of ancient Japanese abortion crimes and criminal law"

<https://news.yahoo.co.jp/articles/2882ecb5c6d3fee7420c900f375a494976e3b229>

3. Are medical abortion pills deleterious drugs containing a poisonous ingredient? No!

by Kumi Tsukahara

In Japan, Linepharma KK's Mefeego Pack (the brand name of the combi-pack of abortion pills mifepristone and misoprostol) was finally approved on 28 April 2023, but labelled as “deleterious”, 35 years later than their approval in France. As for their components, both the formulation and the active ingredient of mifepristone and the formulation of misoprostol were classified as “deleterious”, meaning “causing harm or damage”.

Moreover, in July 2023, the Japanese Ministry of Health, Labour and Welfare (MHLW) abruptly designated the active ingredient of misoprostol in the Mefeego Pack as a "poison". They apparently decided to adopt Cytotec's description of the active ingredient of misoprostol, which according to the [EMC website](#) (the company that sells Cytotec) is based on the use of Cytotec for treatment of gastric ulcers. And they have already had Linepharma rewrite their documents accordingly.

Japanese pharmacists tend to regard such classifications of medicines as not a major concern. However, given that this drug is a World Health Organization (WHO) approved essential medicine that could and should be made as widely available as possible, the designation of misoprostol as a deleterious drug and the accompanying restrictions are surely serving as barriers to access. Mefeego Pack's conditions of approval also include strict control of who can be a provider and who can prescribe and monitor use – that is, a “designated” obstetrician/gynaecologist under the Maternal Protection Act. They also include forced hospitalisation of the woman or her remaining in a medical institution until the expulsion of the fetal sac, as well as with multiple requirements for distribution and medication controls.

In these conditions, patients are deprived of the best aspects of medical abortion, including privacy and self-management, and are even deprived of freedom of movement. Spousal consent is still required, as with all abortions, and the fee is said to be around 100,000 yen (about US\$700), equivalent to the cost of a surgical abortion, which is not covered by health insurance. Confined to the island nation of Japan, one tends to lose sight of such injustices.

The combination of mifepristone and misoprostol for medical abortion has been recognised around the world as safe and effective for many years. Yet, before it was approved, the MHLW spread the image of the (illegally imported) abortion pills as being dangerous. Designating the pills as "deleterious drugs", let alone as “poison”, could deepen people's misconceptions.

I have spent the past 20 years researching the problems surrounding abortion in Japan from multiple perspectives. I have also met many foreign experts and seen firsthand how hopelessly different Japan's abortion care is from the rest of the world. The problems include more than just abortion as well. For example, the birth control pill was finally approved in Japan only in 1999, some 40 years later than the rest of the world, and even now the utilisation rate is only 2-3%. I am increasingly concerned that the same fate may befall the abortion pills.

Surely, the use of “deleterious” and “poisonous” as labels should be understood as creating a false and fear-based reason to force medical abortions up to 12 weeks, which could safely take place at home, and those after 12 weeks that could take place as day cases managed by a trained nurse or midwife, to take place in in-patient hospital beds and ensure that the fees paid for abortion care are as high as those for D&C.

Recently I also realised that Japanese women will not be able to use additional misoprostol to complete their abortions, if needed, after using the pills in the Mefeego Pack. Yet it has been learned in other countries and is on the way to becoming standard practice, that if additional misoprostol is needed and available, almost all abortions would be completed without requiring a surgical procedure. Cytotec, the only misoprostol product in Japan apart from what is in the combi-pack, is "contraindicated for pregnant women," and doctors are reluctant to prescribe it off-label. Even though the purpose would be to complete the termination of the pregnancy.

According to Dr Sam Rowlands, Visiting Professor at Bournemouth University in the United Kingdom, there are few countries that approve misoprostol alone for abortion. It is basically a treatment for gastric ulcers, and no company dared to submit for the approval of an additional indication that might involve them in potential abortion controversies. Instead, they count on doctors using it off-label to earn the company some extra money.

Yet the Japanese Association of Obstetricians and Gynecologists (an association of many of the “abortion designated” doctors) explicitly prohibits off-label use as follows:

“Off-label use is strictly prohibited because if you use the drug in the same way as other drugs (prescribing for additional dosing, comorbid abortion, or emergency contraception), it will cause inconvenience to fill out the Mefeego Pack Application Report that must be submitted monthly to your medical association, and you can expect to receive guidance from your medical association.”

In this prohibition, the convenience of document processing that must be followed due to "strict control" appears to take precedence over women's health and good clinical practice.

While examining the detailed product description of Cytotec, also labelled a “deleterious drug,” to see if there was any possibility of using it as an add-on to the Mefeego Pack, I was puzzled to find that its active ingredient, misoprostol, has been designated as a "poison". This designation seems to be due to the results of a safety test carried out on animals in 1985, called the [Reproductive and Developmental Toxicity Study](#). In fact, this paper was the same one that MHLW officials had previously cited as the basis for labelling the pills in the Mefeego Pack as deleterious drugs. The toxicity study results identified the risk of birth defects and of induced miscarriage in the fetuses of rabbits exposed to misoprostol. However, an incredibly large dose of misoprostol had been used in these toxicology tests. Specifically, the study reported that “oral administration of 990 µg/kg of Cytotec to rabbits” resulted in post-implantation death or increased organogenesis abnormalities in the rabbit fetuses.

Cytotec taken as a treatment for gastric ulcers is usually at a dose of 200 µg four times a day, for a total daily dose of 800 µg. In contrast, the dose administered in the rabbit experiment, when converted to a human being weighing 50 kg, was 49,500 µg, or about 62 times the normal dose, which is equivalent to taking nearly 250 misoprostol tablets at one time for the human being. Everyone knows that even mere salt will kill you if taken in comparably large quantities. I am not a pharmacologist, but it seems insane to me that misoprostol was designated as “deleterious” and/or “poisonous” based on the results of giving rabbits such an extraordinarily large dose.

“There are human data now, after decades of experience; it seems odd to go back to animal studies,” Professor Rowlands said when I asked about the relationship between abortion drugs and malformation. He referred me to a [letter published in the Lancet in 1998](#), which found that the prostaglandin gemeprost had been associated with a few isolated reports of fetal malformation when, in rare cases, the woman had taken the pills following the failure of the medication and later decided to continue the pregnancy. However, the letter also clearly stated:

“There were no reported cases of malformation associated with use of misoprostol when used with mifepristone.”

Gemeprost is the ingredient of the first abortion medication, Preglandin Vaginal Suppository 1 mg, which was developed in the 1970s and approved in 1984 in Japan. Gemeprost has been used exclusively for mid-term abortions in Japan for the past four decades, and it too is strictly controlled as a deleterious drug. The Japanese designated abortion doctors have demanded that the Mefeego Pack be managed as strictly as Preglandin.

The drug information for Preglandin notes that it “should not be used to induce labour in the delivery of a live baby” because “clinical trials of the drug were conducted only in patients in the second trimester of pregnancy who required therapeutic abortion, and its effects on the fetus were not studied at all”. While Mefeego Pack medications are listed as “deleterious drugs” because of possible adverse effects on “a fetus that survives a failed abortion”, Preglandin has never been considered for its effects on a fetus that survives a failed abortion. In fact, according to newspaper reports at the time of the approval, Preglandin was placed under strict control as a “deleterious drug” because of the intense opposition from conservative representatives and designated doctors themselves objecting to the idea of “abortion by medication alone”.

In fact, Preglandin had been trialled for early abortions in the 1970s and attracted national and international attention with its high success rate. However, Japanese abortion-designated doctors, who were accustomed to performing early abortions by curettage, hid the data on early abortions and pressed the pharmaceutical company to apply for approval of the drug exclusively for mid-term abortions. Only 63 patients used Preglandin in the clinical trial at the time. In the 1990s, several cases of uterine rupture and

cervical lacerations were reported with the use of preglandin, and in 1996, the then Ministry of Health and Welfare further tightened the handling rules and issued a warning.

During this whole period of time, most Japanese doctors were unaware of the increasing use of abortion pills around the world. In a survey I did as part of my research on designated abortion doctors in 2010, the majority of doctors answered that RU486 (mifepristone) was “dangerous”, about 70% said it was “ineffective”, about 60% said it was “difficult to introduce”, and about 50% “opposed its introduction”. Thus, many designated doctors were not aware, even then, that the WHO had positioned abortion pills as a safe and reliable method of pregnancy termination.

Japan had long had the Internet, yet was isolated from the situation overseas. Abortion in Japan must change, and for that we should discuss it across borders.

Experts around the world, including WHO and FIGO, have recognised that the combination of mifepristone and misoprostol at the recommended regimens are very safe for abortions in both the first and second trimester. To designate them as deleterious or poisonous drugs today, based on [outdated literature from 1985](#), only serves to delegitimise the medical professionals and others who know it is safe to use these abortion medications, and also violates the rights of women and girls seeking an abortion.

About the author:

Kumi Tsukahara is a self-employed researcher on Japanese abortion issues. She is the author of three books on abortion issues in Japanese, and also a Japanese translator of Tiana Norgren’s “Abortion before Control”, Heren Hardacre’s “Marketing the Menacing Fetus in Japan” and Robin Stevenson’s “My Body My Choice.”

