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# Policy design for the deregulation of emergency contraceptive pills in Japan through insights from experienced Swiss pharmacists

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#### Abstract

The aim of this study is to research pharmacists' perspectives on emergency contraceptive pill (ECP) regulations in Switzerland, where they have been sold requiring the consultation of a pharmacist for over 20 years, to facilitate policy design concerning the deregulation of ECPs in Japan.

A web-based questionnaire survey was conducted targeting all pharmacists working in community pharmacies in Switzerland, and 150 completed questionnaires were collected (2.6% response rate). 95.4% of respondents rated the current system as appropriate, and 96.7% of respondents answered that the current regulations should be kept unchanged. It ensures drug safety through an in-person consultation with the pharmacist, which is considered necessary (89.3% of respondents); but provides easy access to ECPs (88.7% of respondents). Dealing with sexual violence victims is considered most difficult (93.3% of respondents). Furthermore, compared to pharmacists with less than 20 years of working experience, those with over 20 years of experience were more likely to rate the time burden for the pharmacist due to conducting consultations as difficult ( $\gamma^2$  test, 13.0% vs. 27.2%, p = 0.033).

In conclusion, Switzerland's ECP regulations offer safety and easy access and could therefore be appropriate for implementation in Japan. Training pharmacists on communication with adolescents and sexual violence victims is vital.

#### Keywords

Emergency contraceptive pills; levonorgestrel; Switzerland; community pharmacist; over-the-counter

#### Introduction

Emergency contraceptive pills (ECPs) containing levonorgestrel are taken within 3 days after unprotected intercourse and act by postponing or inhibiting ovulation<sup>1)</sup>. They are also used to prevent pregnancies if the primary contraception method failed. ECPs are especially valuable for women who experienced rape or sexual violence, and they are included in the World Health Organization (WHO)'s Model List of Essential Medicines and the current WHO Guideline on Self-Care Interventions for Health and Well-Being <sup>2,3)</sup>.

In Japan, only ECPs containing levonorgestrel have been approved; the brand name drug NorLevo® in 2011, and the generic version in  $2019^{4.5}$ . We will thus use the term ECPs to refer to levonorgestrel EPCs hereinafter. Currently, the drug

is classified as prescription-only, which means that it is available directly from doctors or at a pharmacy with a physician's prescription. Since 2019, the physician's consultation can also take place online. However, pharmacists must undergo training to be able to dispense the drug on online prescriptions<sup>6)</sup>. While the number of trained pharmacists has been increasing recently, access can still be insufficient in rural areas, as well as on weekends and national holidays, making it difficult for women to be able to take the drug within the required 72 hours after unprotected intercourse<sup>5)</sup>. In its Fifth Basic Plan for Gender Equality, the Cabinet of Japan stated in 2020 that ECPs should be made available without prescription from trained pharmacists following an in-person consultation7), corresponding to behind-the-counter (BTC) status of the drug. In

\* Corresponding author 齋藤 カルメン 〒283-8555 千葉県東金市求名1番地 Gumyo 1, Togane-shi, Chiba 283-8555, Japan E-mail address: csaito@jiu.ac.jp TEL: 0475-53-4529 FAX: 0475-53-4556 accordance with this plan, the Ministry of Health, Labour and Welfare (MHLW) started preparing a pilot sale in select pharmacies in collaboration with the Japan Pharmaceutical Association (JPA), to research the ideal conditions for the sale of ECPs in pharmacies. The pilot sale started in November 2023, and currently includes 145 pharmacies from all prefectures. Pharmacies which have a private consultation space, are available on weekends and holidays, and employ pharmacists who have completed training to dispense ECPs on prescription are able to participate in the pilot sale<sup>8)</sup>.

On the other hand, in Switzerland, ECPs have been available in pharmacies since 2002<sup>9)</sup>. ECPs are classified as BTC drugs, requiring a consultation with the pharmacist before purchase. All pharmacists are trained on the sale of ECPs, so the drug can be obtained at any time during the opening hours of the pharmacy without an appointment. There are no age limits and pharmacists use an official checklist during the consultation. It is not required to take the drug in the pharmacy; however, it is recommended to do so to prevent a delay in treatment<sup>10)</sup>.

The reason for selecting Switzerland as the target of our study is that its ECP regulations closely

resemble the recommendations that the Cabinet of Japan proposes for implementation. As mentioned above, the Cabinet of Japan recommends ECPs to be available from trained pharmacists following an in-person consultation. This corresponds to a classification of drugs requiring special instruction (youshidou-iyakuhin) in Japan, for which online sale is not permitted. Looking at ECP regulations in several countries, BTC sale without permission of online sale is only practiced in Germany and Switzerland<sup>11)</sup> (Table 1). Switzerland, having practiced these regulations for 22 years compared to Germany's 9 years, presents an ideal study target due to Swiss pharmacists' greater experience in selling ECPs.

Comparing the medical and social backgrounds of Switzerland and Japan, both have a health insurance system with mandatory enrolment, drug pricing is government-regulated and ECPs are not covered by health insurance (Table 2). ECPs are also available by prescription in Switzerland; however, this is rarely practiced due to the easy availability in pharmacies. There are 2.3 times more pharmacies and 3.2 times more pharmacists per 100,000 population in Japan than in Switzerland. Because of the similarities in the regulatory and insurance

Country	Classification	Year <sup>a</sup>	Price <sup>b</sup>	Online sale
Canada	OTSc/BTCd	2000	9.58-24.13	Yes
France	BTC	1999	0	Yes
Germany	BTC	2015	17.41-20.13	No
Italy	BTC	2015	11.96-18.77	Yes
United Kingdom	BTC	2001	0-31.21	Yes
United States of America	OTS	2006	40-50	Yes
Switzerland	BTC	2002	46.18-48.96	No

<sup>&</sup>lt;sup>a</sup> year ECPs were made available without a prescription

<sup>&</sup>lt;sup>b</sup> price in US dollars including subsidies and consultation fees

<sup>&</sup>lt;sup>c</sup> on-the-shelf, meaning the product can be taken from the shelf by the customer and be purchased without questions from the staff.

<sup>&</sup>lt;sup>d</sup> behind-the-counter, meaning the product is kept behind the pharmacy counter and must be requested by the costumer. There might be a consultation with the pharmacist before purchasing.

Table 2: Comparison of medical and social backgrounds in Japan and Switzerland

	Japan	Switzerland
Health insurance	Mandatory enrolment	Mandatory enrolment <sup>12</sup>
Drug pricing	Government-regulated	Government-regulated <sup>13</sup>
Pharmacies (per 100,000 population)	49.9 <sup>14</sup> (2022)	21.415 (2022)
Pharmacists (per 100,000 population)	259.1 <sup>16</sup> (2022)	80.3 <sup>17,18</sup> (2022)
General pharmacy functions	Dispensing prescription drugs, OTC	Dispensing prescription drugs, OTC
	sale, health advice, home	sale, health advice, vaccination,
	healthcare <sup>19</sup>	selling certain prescription drugs
		without prescription <sup>20</sup>
ECP provision system	On prescription	On prescription
	From pharmacist with an in-person	From pharmacist with an in-person
	consultation (pilot sale)	consultation
ECP health insurance coverage	None	None
ECP yearly use	Unknown*	Unknown*

<sup>\*</sup> Yearly use unknown because not covered by health insurance

frameworks, even though there is a slight difference in the number of pharmacies and pharmacists, Swiss pharmacists' perspectives on ECP regulations could serve as a reference for Japan, especially considering that Swiss pharmacies manage ECP distribution with a lower pharmacy density than Japan.

The aim of this study is to 1) evaluate the perspectives of Swiss pharmacists on ECP regulations in Switzerland including sale conditions, 2) assess their views on the difficulties when selling ECPs and 3) to determine their attitudes towards how to further improve access to ECPs in Switzerland, to gain insights which could facilitate Japan's policy design.

#### Methods

### Study design

We conducted a web-based survey using Google forms to examine the views of Swiss pharmacists on ECP regulations. The first half of the questionnaire (questions 1-18) was based on the one used in our previous study on the views of Japanese community pharmacists on ECP regulations<sup>21)</sup>. The questionnaire was first created in English for an

international audience, then translated into German and French. The translated questionnaire was checked and pilot tested by two Swiss pharmacists experienced in ECP consultations and native in the respective languages. The finalized questionnaire contained 32 questions (including 27 questions with predetermined answers generally using a five-point Likert scale, and five optional long-form questions) and demographics. The following topics were surveyed by the questionnaire: frequency of dispensing ECPs, perspectives on the current system of dispensing ECPs, views on the current sale conditions for ECPs, difficulties encountered when selling ECPs, as well as attitude towards further facilitating access to ECPs in Switzerland.

Swiss pharmacists currently working in a community pharmacy were selected as the subjects of the study, amounting to 5,753 pharmacists according to the Swiss Association of Pharmacists (pharmaSuisse)<sup>15</sup>. Recruitment occurred through pharmaSuisse's monthly newsletter on February 13, 2024. Data was collected up until March 31, 2024. The study was conducted anonymously, and participation was voluntary. The completion of the online questionnaire was regarded as consent to

study participation. The study was approved by the Ethics Review Board for Research Involving Human Subjects of Josai International University, Japan (No. 23X230029).

#### Statistical analysis

Descriptive statistics were used to describe 1) respondents' characteristics, 2) pharmacists' perspectives on ECP regulations and sale conditions, 3) views on difficulties when selling ECPs and 4) attitudes towards further facilitating access to ECPs in Switzerland.

Except for respondents' characteristics, the respondents answered to the questions in each category mentioned above on a five-point Likert scale, with a final optional long-form question for additional comments. To show overall agreement or disagreement with the statements given in the questionnaire, the answers were dichotomized

as follows: agree (agree, rather agree) vs. others (neutral, rather disagree, disagree), necessary (necessary, rather necessary) vs. others (neutral, rather unnecessary, unnecessary), as well as difficult (difficult, rather difficult) vs. others (neutral, rather easy, easy). For detailed analysis of categories 2) to 4), the pharmacists were split in two groups based on their working experience: less than 20 years and over 20 years, meaning if they were already working as pharmacists when ECPs became available without prescription or not. To evaluate the difference in views between them,  $\chi^2$  tests were used and a p-value of less than 0.05 was considered statistically significant.

Statistical analyses were conducted using the statistical software SPSS (IBM SPSS Statistics for Windows, Version 29.0.1, IBM Corp., Armonk, NY, USA) and Microsoft Excel (Microsoft Excel for Microsoft 365 MSO, Version 2403).

Table 3: Respondents' characteristics (n = 150)

		n	%
Gender	Female	114	76.0
	Male	36	24.0
Age	Under 30 years old	13	8.7
	30-39 years old	36	24.0
	40-49 years old	32	21.3
	50-59 years old	39	26.0
	Over 60 years old	30	20.0
Language	German	105	70.0
	French	45	30.0
Working experience	Less than 5 years	19	12.7
	5-9 years	17	11.3
	10-19 years	33	22.0
	20-29 years	35	23.3
	Over 30 years	46	30.7
Experience in selling ECPs	Less than once per month	18	12.0
	1-9 times per month	111	74.0
	10-19 times per month	11	7.3
	20-39 times per month	3	2.0
	Over 40 times per month	7	4.7
Pharmacy opening hours	Open on Sundays	19	12.7
	Others	131	87.3

#### Results

#### Respondents' characteristics

Up until March 31, 2024, 150 completed questionnaires were collected via Google Forms (2.6% response rate). Of these, 105 were completed in German and 45 in French. Women were overrepresented, with over three quarters of respondents. Except for under 30 years old, all age groups were rather equally represented. Most respondents (74.0%, n = 111) answered that they dispensed ECPs 1-9 times per month (Table 3).

Even though our survey showed a very low response rate, age and gender distribution of the participants closely matched those of all Swiss pharmacists (Table 4), except for the over 60 years old age group being slightly overrepresented.

Table 4: Age and gender distribution of pharmacists in Switzerland<sup>22</sup>

		%
Gender	Female	76.5
	Male	23.5
Age	Under 30 years old	9.1
	30-39 years old	27.8
	40-49 years old	22.1
	50-59 years old	27.5
	Over 60 years old	13.6

# Perspectives on ECP regulations and sale conditions

Currently, most Swiss pharmacists (88.7%, n = 133) view ECP access from the patients' perspective as easy (easy or rather easy). Likewise, the current regulations are seen as appropriate (appropriate or rather appropriate) by 95.4% (n = 143) of respondents (Table 5).

Correspondingly, almost all respondents (96.7%, n=145) stated that regulations should be kept the same as currently. Only 5 respondents agreed with regulations being loosened (Table 5).

Almost all respondents found conducting the consultation in a separate room (95.3%, n=143) and dispensing according to official guidelines (93.3%, n=140) necessary when selling ECPs (Table 6). Other sale conditions considered necessary were the personal consultation with the pharmacist (89.3%, n=134) and the use of the official dispensing protocol (83.3%, n=125).

As an optional long-form question, pharmacists were asked if there was anything else that was necessary when selling ECPs. The most frequently given answers were that pharmacists should keep a non-judgmental attitude during the consultation (8 respondents) and that they should be open to answer any questions from the customers (5 respondents).

Table 5: Swiss pharmacists' perspectives on ECP regulations (n = 150)

		n	%
ECP access difficulty from the	Difficult	1	0.7
customers' perspective	Rather difficult	5	3.3
	Neutral	11	7.3
	Rather easy	58	38.7
	Easy	75	50.0
Perspectives on the current	Appropriate	133	88.7
regulations	Rather appropriate	10	6.7
	Neutral	5	3.3
	Rather inappropriate	0	0.0
	Inappropriate	2	1.3
Perspectives on future ECP	Only with prescription (stricter regulation than currently)	0	0.0
regulations	After consultation with the pharmacist (current regulation)	145	96.7
	Free OTC sale (easier access than currently)	5	3.3

Table 6: Perspectives on the necessity of the current sale conditions and measures between respondents with a working experience of less than 20 years vs. over 20 years (n = 150)

			Working experience				
			Less than	20 years	Over 20	years	
	Ove	erall	(n = 69)		(n = 81)		
	nª	%a	nª	0/0 <sup>a</sup>	nª	%a	$p^{b}$
Conducting the consultation in a separate							
room	143	95.3	67	97.1	76	93.8	0.343
Dispensing according to official guidelines	140	93.3	64	92.8	76	93.8	0.793
Personal consultation with the pharmacist	134	89.3	64	92.8	70	86.4	0.210
Use of the official dispensing protocol	125	83.3	55	79.7	70	86.4	0.272
ECP intake directly at pharmacy	112	74.7	54	78.3	58	71.6	0.350
Comprehensive sex education of the public	101	67.3	50	72.5	51	63.0	0.216
Dispensing without age restriction	91	60.7	45	65.2	46	56.8	0.292
Advice on contraceptive methods by the							
pharmacist	87	58.0	43	62.3	44	54.3	0.323

<sup>&</sup>lt;sup>a</sup> Number and percentage of respondents who answered that the given sale conditions and measures are necessary or rather necessary

Table 7: Views on difficulties when selling ECPs between respondents with a working experience of less than 20 years vs. over 20 years (n = 150)

			Working experience				
			Less than	20 years	Over 20	years	
	Ove	rall	(n = 69)		(n = 81)		
	nª	%a	nª	% a	nª	%a	$p^{b}$
Dealing with sexual violence victims	140	93.3	64	92.8	76	93.8	0.793
Dealing with very young customers (under							
16 years old)	70	46.7	28	40.6	42	51.9	0.168
Dealing with customers who repeatedly							
request ECPs	63	44.7	30	43.5	37	45.7	0.787
Time burden for the pharmacist due to							
conducting consultations	31	20.7	9	13.0	22	27.2	0.033*
Dealing with the partner of the customer	23	15.3	11	15.9	12	14.8	0.849

<sup>&</sup>lt;sup>a</sup> Number and percentage of respondents who answered that the given situations are difficult or rather difficult to deal with when selling ECPs

 $<sup>^{</sup>b}$   $\chi^{2}$  test between respondents with a working experience of under 20 years vs. over 20 years

<sup>&</sup>lt;sup>b</sup> χ<sup>2</sup> test between respondents with a working experience of less than 20 years vs. over 20 years

<sup>\*</sup> p < 0.05

#### Views on difficulties when selling ECPs

Most respondents (93.3%, n = 140) found dealing with sexual violence victims difficult during ECP consultations (Table 7). Dealing with very young customers under 16 years old (46.7%, n = 70), dealing with customers who repeatedly request ECPs (44.7%, n = 63), the time burden for the pharmacist (20.7%, n = 31) and dealing with the partner of the customer (15.3%, n = 23) were only seen as difficult by less than half of the respondents.

Compared to pharmacists with less than 20 years of working experience, pharmacists with over 20 years of working experience were more likely to find the time burden for the pharmacist difficult ( $\chi^2$  test, 13.0% vs. 27.2%, p = 0.033).

Two respondents commented on the difficulties of dealing with sexual violence victims. One noted that it is difficult to recognize instances of sexual violence, while the other pointed out that pharmacies are not the appropriate places for counseling victims. While pharmacists can refer victims to specialized services, they cannot ensure that the individual follows through with seeking the necessary help.

# Attitudes towards facilitating access to ECPs in Switzerland

Only a very small number of respondents agreed to the proposed strategies for further facilitating access to ECPs in Switzerland. Dispensing free of charge showed the most agreement (8.0%, n = 12) (Table 8).

Compared to pharmacists with over 20 years of working experience, pharmacists with less than 20 years of working experience were more likely to agree that dispensing free of charge ( $\chi^2$  test, 3.7% vs. 13.0%, p = 0.036) would be a good strategy for facilitating access to ECPs.

When asked if there was anything else that could be done to facilitate access to ECPs in Switzerland, the most frequent answers were that consultations could also be conducted by trained pharmacy technicians (4 respondents) and that the price should be lower (3 respondents). 2 respondents mentioned that education about ECPs should be improved, for example through trained pharmacists as guest lecturers in schools (1 respondent).

Finally, pharmacists were asked if there was anything else they wanted to say about ECP sale in Switzerland. 10 respondents answered that they

Table 8 : Attitudes towards facilitating access to ECPs in Switzerland between respondents with a working experience of less than 20 years vs. over 20 years (n = 150)

			7	xperience			
			Less than	20 years	Over 20	years	
	Ove	erall	(n = 69)		(n = 81)		
	na	%a	nª	% <sup>a</sup>	nª	%a	$p^{b}$
Dispensing free of charge	12	8.0	9	13.0	3	3.7	0.036*
24-hour on-call service for all pharmacies							
dispensing ECPs	7	4.7	5	7.2	2	2.5	0.167
Free OTC sale (no consultation) with age							
restriction (over 18 years)	7	4.7	2	2.9	5	6.2	0.343
Dispensing in advance	6	4.0	1	1.4	5	6.2	0.141
Free OTC sale (no consultation) without age							
restriction	2	1.3	1	1.4	1	1.2	0.909
Enabling online sale	2	1.3	1	1.4	1	1.2	0.909

<sup>&</sup>lt;sup>a</sup> Number and percentage of respondents who agreed or rather agreed to the given strategies for facilitating access to ECPs

 $<sup>^{</sup>b}$   $\chi^{2}$  test between respondents with a working experience of less than 20 years vs. over 20 years

<sup>\*</sup> p < 0.05

perceived the current system in Switzerland with pharmacists as gatekeepers as ideal, and that a consultation was necessary when selling ECPs.

#### Discussion

Our study showed a high degree of satisfaction with the current ECP regulations in Switzerland from the perspective of pharmacists; 95.4% of respondents rated the current system as appropriate, and 96.7% of respondents answered that the current regulations should be kept unchanged. Reasons for this could include that, while a personal consultation with the pharmacist is considered necessary (89.3% of respondents), the current system is still believed to provide easy access to ECPs (88.7% of respondents). In Switzerland, ECP consultations are offered in every pharmacy during all opening hours without an appointment, which could be why it was not seen as a hurdle to ECP access by the respondents. On the other hand, none of the strategies to facilitate access to ECPs in Switzerland proposed in the survey received a substantial amount of support from the respondents. Only 8.0% of respondents agreed that ECPs should be distributed free of charge, while less than 5% of respondents agreed to a 24-hour on-call service for all pharmacies dispensing ECPs, free OTC sale (no consultation) with or without age restriction, dispensing in advance, and online sale. However, it is important to note that these findings are based on a survey with a very low response rate, which may limit the representativeness of the results.

Currently, the Cabinet of Japan recommends implementing a system where ECPs can be purchased without prescription in-person from trained pharmacists. Switzerland has been practicing such a system for over 20 years. As mentioned above, most respondents answered that Switzerland's current system should be kept unchanged, because it provides easy access to ECPs for customers, while still ensuring drug safety by pharmacists acting as gatekeepers. In our previous study, 90.8% of Japanese community pharmacists rated current ECP access in Japan as difficult, which could be improved if ECPs became available without prescription<sup>19)</sup>. However, under Japan's current

drug regulations, prescription drugs switched to OTC status will only have 'drug requiring special instruction' (requiring an in-person consultation by the pharmacist) status for three years. After that, they will automatically change to the next category of 'class 1 drugs' and, while still under the supervision of a pharmacist, online sale will become possible<sup>23)</sup>. As we were able to show, only 1.3% of Swiss pharmacists agreed to enabling online sale for ECPs. Therefore, regulatory changes which would allow ECPs to stay at 'drug requiring special instruction' status permanently should be considered.

Requiring a consultation by the pharmacist also provides an opportunity for the pharmacist to educate the customer about the female cycle, ECPs and contraceptives in general. In the current study, only 67.3% of pharmacists deemed comprehensive sex education of the public as necessary, compared to 95.4% of Japanese pharmacists in our previous study<sup>21)</sup>. This shows that there is a stronger need for sex education in Japan. Currently, while pregnancy and birth are taught in high school (15-18 years of age), knowledge on contraception is not part of Japan's junior high school (12-15 years of age) and high school curriculum<sup>24)</sup>. On the other hand, Swiss students first learn about contraception in grade 3-6 (8-12 years of age), and detailed knowledge on contraceptive methods and the responsibility of both sexes for conception and contraception is taught in grade 7-9 (12-15 years of age)<sup>25)</sup>. Although providing sex education to customers during ECP consultations would partially address the public's need for sex education in Japan, it is not sufficient to improve sex education for the entire population. Further research is needed assess the current state of sex education for adults. Pharmacists should be trained to effectively conduct sex education. These trained pharmacists could also serve as guest lecturers to enhance sex education in schools, as mentioned by a respondent in our study.

Currently, the ECP pilot sale in Japan requires customers to be over 16 years old, with customers 16 and 17 years old requiring parental consent<sup>8)</sup>, because consent to the research study is required for purchase. There is no age limit for ECP sale in

Switzerland<sup>10)</sup>. In our study, 60.7% of respondents found that selling ECPs without age restrictions was necessary. However, dealing with customers under 16 years of age was still seen as difficult by almost half of the respondents. The reason that ECPs are available without age restrictions in many countries could be that for adolescents, a pregnancy would have serious social and economic consequences for their lives. This is especially true for adolescents who are victims of abuse in or out of the household, or have no adult to confide in for other reasons. In 2022, there were 403 abortions for under 16-year-olds, and 2,175 abortions for 16 and 17-year-olds in Japan, which shows that there is a need for emergency contraception in this age group 14). Recently, the Tokyo Metropolitan Government has started a program in which adolescents who seek advice about ECPs from the Tokyo Youth Health Support Centre 'Wakasapo' can opt to be accompanied to medical institutions by a nurse<sup>26)</sup>. If such Sexual Health counselling services were offered at every municipality's Health Centre (hokenjo) in Japan, especially but not only for adolescents and sexual violence victims, professionals could accompany minors to the pharmacy to acquire ECPs. This would greatly improve ECP access for minors, especially those who are unable to confide in their parents or other guardians, while still maintaining adequate care provided by the Health Centre's professionals.

Correspondingly, to be able to offer ECPs in pharmacies without age restrictions in Japan, pharmacists should receive training on how to approach very young customers. Furthermore, even though Swiss pharmacists have over 20 years of experience in selling ECPs in pharmacies, 93.3% of the respondents in our study find dealing with sexual violence victims difficult. While pharmacists are not specialised in counselling those customers, they should be educated on how to best communicate with them and where to refer them to after providing them with ECPs.

Moreover, whereas the current ECP pilot sale in Japan requires participating pharmacies to have a private consulting space or room, over 95% of Swiss pharmacists rated conducting the ECP consultation in a separate room as necessary. However, even

though not all pharmacies participating in the pilot sale had a separate consulting room, the initial results of the pilot sale show that 97.2% of customers were satisfied with the privacy considerations<sup>27)</sup>. This demonstrates that while a separate room might be ideal, a private consulting space may be sufficient if the pharmacy implements other privacy measures, such as playing ambient sounds or the pharmacist paying attention to talking volume. For the deregulation of ECPs in Japan, requiring only a private consulting space instead of a consulting room would place less of a burden on pharmacies looking to start selling ECPs. The pharmacy infrastructure could then be gradually updated to include consulting rooms. In Switzerland, consulting rooms were also not available in every pharmacy when ECPs became available without a prescription. They have only become more common since 2015, when pharmacists began conducting vaccinations20).

In our study, we also compared the views of pharmacists with less than 20 years of working experience to those of pharmacists with over 20 years of working experience. First, pharmacists with over 20 years of working experience were more likely to rate the time burden of conducting consultations as difficult. This may be because experienced pharmacists often take on roles as pharmacy manager or owner, which involve operational, financial, and staff training responsibilities that take up a significant amount of their time. In Switzerland, pharmacists with less than 20 years of working experience who graduated after ECPs became available without a prescription have been educated about ECPs at university. Considering this in the context of the deregulation of ECPs in Japan, content on ECP consultations should be integrated into the pharmacy school curriculum so that young pharmacists receive training in ECP consultations first. This would help reduce the burden on more experienced pharmacists, allowing them to focus on other responsibilities. Second, pharmacists with less than 20 years of working experience were more likely to agree that dispensing ECPs free of charge would be a good strategy to improve access to ECPs. This might be due to a difference

in values considering sexual and reproductive health and rights because of a generational gap. The topic of reproductive health and rights has gained popularity recently; however, it was only first defined at the International Conference on Population and Development in  $1994^{28}$ . Therefore, younger pharmacists are more likely to have grown up with the concept of reproductive rights, which might lead them to believe that providing ECPs free of charge is necessary to protect these rights.

#### Further research

As mentioned above, when ECPs are introduced as OTC drugs in Japan, they should stay at 'drug requiring special instruction' status without online sales. However, further research should be conducted to explore the views of pharmacists in countries where ECP regulations have loosened over time. This would help understand why regulations were loosened as well as provide insights on how to implement similar policies in Japan, should the need arise in the future. Moreover, research should be conducted on the perspectives of customers on ECP access, because they are most affected by access difficulties.

#### Limitations

The biggest limitation of our study was the very low response rate resulting in a small sample size. A reason for this could have been that the survey was distributed during winter, which is a work intensive period for pharmacists due to the prevalence of respiratory illnesses. However, the main reason was likely that recruitment for the survey occurred through the Swiss Association of Pharmacists' monthly e-mail newsletter, in contrast to addressing each pharmacist personally. While the newsletter often features similar surveys, many pharmacists might not have read the newsletter or might not have been interested in the topic of the survey. This leads to the assumption that there is a possibility of selection bias among the respondents, as only pharmacists who have an interest in ECPs may have participated. Further studies should be planned to explore the views of Swiss pharmacists on ECPs, such as through an in-person survey at a conference or by using a market research company to acquire

data from a representative sample of respondents.

#### Conclusion

In Japan, deregulation of ECPs is currently being discussed to improve access to the drug. Considering policy design, regulations similar to Switzerland's could be appropriate, since they showed a high degree of satisfaction among the pharmacists participating in our study. Reasons for this are that while pharmacists acting as gatekeepers ensures drug safety, ECPs being available at every pharmacy during all opening hours without an appointment still provides easy access to the drug. Pharmacists should be trained to effectively conduct sex education so that they can provide information about the female cycle and contraception during consultations, which would help improve public sex education in Japan. Additionally, these trained pharmacists could serve as guest lecturers in schools to teach about topics such as contraceptive methods.

To offer ECPs in pharmacies for women of all ages in Japan, Sexual Health counselling services should be implemented in every municipality, and pharmacists should be trained on how to appropriately communicate with adolescent customers and sexual violence victims.

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#### Conflict of interest

The authors report there are no competing interests to declare.

#### References

 Endler M, Li R, Gemzell Danielsson K: Effect of levonorgestrel emergency contraception on implantation and fertility: A review. Contraception, 109, 8-18, 2022. doi: 10.1016/ j.contraception.2022.01.006

- 2) World Health Organization: WHO Model List of Essential Medicines – 23<sup>rd</sup> list, 2023. https://iris. who.int/bitstream/handle/10665/371090/WHO-MHP-HPS-EML-2023.02-eng.pdf [accessed 2024 Apr 16]
- 3) World Health Organization: WHO guideline on self-care interventions for health and well-being, 2022 revision. https://iris.who.int/bitstream/handle/10665/357828/9789240052192-eng.pdf [accessed 2024 Apr 16]
- 4) Pharmaceuticals and Medical Devices Agency (PMDA): Approval list (new drugs, april 2010 march 2011), 2011 [Japanese]. https://www.pmda.go.jp/files/000160448.pdf [accessed 2024 Apr 16]
- 5) Pharmaceuticals and Medical Devices Agency (PMDA): Drug interview form. Levonorgestrel tablets 1.5mg, 2019 [Japanese]. https://www.info.pmda.go.jp/go/interview/1/670109\_254900AF20 32\_1\_004\_1F.pdf [accessed 2024 Apr 16]
- 6) Ministry of Health, Labor and Welfare (MHLW). Initiatives related to emergency contraception, 2023 [Japanese]. https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000186912\_00002.html [accessed 2024 Apr 16]
- 7) Cabinet of Japan; Gender Equality Bureau Cabinet Office: Fifth Basic Plan for Gender Equality. Field 7: Life-long Health Support, 2020 [Japanese]. https://www.gender.go.jp/about\_danjo/basic\_plans/5th/pdf/2-07.pdf [accessed 2024 Apr 16]
- 8) Japan Pharmaceutical Association: Emergency contraceptives test-marketed at select pharmacies information, 2023 [Japanese]. https://www.pharmacy-ec-trial.jp [accessed 2024 Apr 16]
- 9) Barrense-Dias Y, Stadelmann S, Suris J-C, et al: From request to dispensation: how adolescent and young adult females experience access to emergency contraception in pharmacies. Eur J Contracept Reprod Health Care, 27, 403-8, 2022. doi: 10.1080/13625187.2022.2093849
- 10) pharmaSuisse: Comments on the dispensing protocol for oral emergency contraception, 2022 [German]. https://www.sexuelle-gesundheit.ch/assets/docs/2022\_Kommentare-zum-Abgabeprotokoll.pdf [accessed 2024 May 8]
- 11) Saito C, Kobayashi E: Comparison of Emergency

- Contraceptive Pill Regulations in Other Highly Developed Countries and Policy Recommendations for the Deregulation in Japan. Reg Sci Med Prod 2024, 14, 65-80, 2024. doi: 10.14982/rsmp.14.65
- 12) Federal Office of Public Health: Health insurance. https://www.bag.admin.ch/bag/en/home/versicherungen/krankenversicherung.html [accessed 2024 Sep 10]
- 13) Federal Office of Public Health: Pharmaceuticals and medicinal products. https://www.bag.admin.ch/bag/en/home/versicherungen/krankenversicherung/krankenversicherungleistungen-tarife/Arzneimittel.html [accessed 2024 Sep 10]
- 14) Ministry of Health, Labour and Welfare (MHLW): Summary of public health reports in 2022, 2022 [Japanese]. https://www.mhlw.go.jp/toukei/saikin/hw/eisei\_houkoku/22/dl/gaikyo.pdf [cited 2024 May 1]
- 15) pharmaSuisse: Facts and numbers of Swiss pharmacies, 2022 [German]. https://pharmasuisse.org/system/files/media/documents/2023-04/Fakten-und-Zahlen-pharmaSuisse-2022.pdf [accessed 2024 Apr 16]
- 16) Ministry of Health, Labour and Welfare (MHLW):
  Summary of Statistics on Physicians, Dentists and
  Pharmacists in 2022, 2022 [Japanese]. https://
  www.mhlw.go.jp/toukei/saikin/hw/ishi/22/dl/
  R04\_1gaikyo.pdf [accessed 2024 Sep 9]
- 17) Bundesamt für Gesundheit (BAG): Statistics on Pharmacists 2022, 2022 [German]. https://www.bag.admin.ch/dam/bag/de/dokumente/berufegesundheitswesen/medizinalberufe/statistiken/pharma/apothekerinnen-und-apotheker-2022.pdf.download.pdf/Apothekerinnen\_und\_Apotheker\_2022\_d.pdf [accessed 2024 Sep 9]
- 18) Bundesamt für Statistik: Permanent and temporary resident population, 2022 [German]. https://www.bfs.admin.ch/bfs/de/home/statistiken/bevoelkerung/stand-entwicklung. assetdetail.32207872.html [accessed 2024 Sep 9]
- 19) Ministry of Health, Labour and Welfare (MHLW): The state of community pharmacies and pharmacists, 2024 [Japanese]. https://www.mhlw.go.jp/content/11121000/001254939.pdf [accessed 2024 Sep 11]

- 20) Amador-Fernández N, Jenkinson SP, Berger J: Vision and practice of self-care for community pharmacy in Switzerland. Explor Res Clin Soc Pharm, 9, 100253, 2023. doi: 10.1016/ j.rcsop.2023.100253.
- 21) Saito C, Kobayashi E: Perspectives on Emergency Contraceptive Pill Regulations: A Survey of Community Pharmacists from Chiba Prefecture Who Have Completed Training to Dispense Emergency Contraceptive Pills on Prescription. J Community Pharm Pharm Sci, 16, 68-75, 2024. doi: 10.32160/yakkyoku.nt.2023-0033
- 22) pharmaSuisse: Facts and numbers of Swiss pharmacies, 2023 [German]. https://pharmasuisse.org/system/files/media/documents/2023-11/A6\_de\_Fakten\_Zahlen\_2023\_web.pdf [accessed 2024 Sep 10]
- 23) Ministry of Health, Labour and Welfare (MHLW):
  About Drugs Requiring Special Instruction,
  2023 [Japanese]. https://www.mhlw.go.jp/
  content/11121000/001062522.pdf [accessed
  2024 Apr 19]
- 24) Ministry of Education, Culture, Sports, Science and Technology (MEXT): Revised Courses of Study for 2017, 2018, and 2019 (text and commentary), 2019 [Japanese] https://www.mext.go.jp/a\_menu/shotou/new-cs/1384661.htm [accessed 2024 Apr 30]
- 25) Deutschschweizer Erziehungsdirektoren-Konferenz: Curriculum 21: Nature, people, society, 2016 [German]. https://v-fe.lehrplan.ch/ container/V\_FE\_DE\_Fachbereich\_NMG.pdf [cited 2024 May 9]
- 26) NHK: Tokyo Metropolitan Government to support young people who need "emergency contraceptives" by accompanying them to medical institutions, 2024 [Japanese]. https://www3.nhk. or.jp/news/html/20240118/k10014324921000. html [accessed 2024 May 1]
- 27) Ministry of Health, Labour and Welfare (MHLW): Survey Project for Improving the Environment for Emergency Contraceptive Sales Report, 2023 [Japanese]. https://www.mhlw.go.jp/content/11120000/001253219.pdf [accessed 2024 Sep 10]

28) United Nations Population Fund: Programme of Action – Adopted at the International Conference on Population and Development, Cairo, 1994. https://www.unfpa.org/sites/default/files/event-pdf/PoA\_en.pdf [accessed 2024 Sep 10]

## Supplementary Material\_Questionnaire with 32 questions and demographics

Questionnaire for Swiss pharmacists about emergency contraceptive pills

- F1 How often do you dispense emergency oral contraception at your pharmacy? (levonorgestrel as well as ulipristal acetate)
  - 1. Less than once per month
  - 2. 1-9 times per month
  - 3. 10-19 times per month
  - 4. 20-39 times per month
  - 5. Over 40 times per month
- F2 In Switzerland, customers receive oral emergency contraception after a consultation with the pharmacist.

  Do you think this system is appropriate?
  - 1. Appropriate
  - 2. Rather appropriate
  - 3. Neutral
  - 4. Rather inappropriate
  - 5. Inappropriate
- F3 From the customer's perspective, how difficult is it to access emergency oral contraception in Switzerland?
  - 1. Difficult
- 2. Rather difficult
- 3. Neutral
- 4. Rather easy
- 5. Easy

The following text and questions refer to emergency contraceptives with levonorgestrel (NorLevo® and generics). To date, free OTC dispensing of levonorgestrel (the product can be taken from the shelf by the customers themselves and purchased without further questions) is allowed in 19 countries, while another 76 countries require dispensing directly by the pharmacist.

- F4 In your opinion, how should oral emergency contraception be dispensed in Switzerland in the future?
  - 1. Only with prescription (more strictly regulated than now)
  - 2. After consultation with the pharmacist (current dispensing regulation)
  - 3. Free OTC dispensing (easier access than now)

# About the $\underline{\text{current dispensing}}$ of emergency oral contraception

How would you rate the <u>necessity</u> of the following <u>current measures</u>?

		Necessary	Rather	Neutral	Rather un-	Un-
			necessary		necessary	necessary
F5	Comprehensive sex education of the general public	5	4	3	2	1
F6	Personal consultation with the pharmacist	5	4	3	2	1
F7	Dispensing according to official guidelines	5	4	3	2	1
F8	Dispensing without age restriction	5	4	3	2	1
F9	Use of the official dispensing protocol	5	4	3	2	1
F10	Taking the drug under the supervision of the pharmacist	5	4	3	2	1
F11	Conducting the consultation in a separate room	5	4	3	2	1
F12	Advice on contraceptive methods by the pharmacist	5	4	3	2	1
F13	Are there any other measures that you consider necessary when dispensing oral emergency contraception?					

How would you rate the  $\underline{\text{necessity}}$  of the following  $\underline{\text{knowledge}}$  for dispensing emergency oral contraception?

		Necessary	Rather	Neutral	Rather un-	Un-
			necessary		necessary	necessary
F14	Female cycle	5	4	3	2	1
F15	How to determine if emergency oral contraception is needed	5	4	3	2	1
F16	Appropriate medication instruction (including contraindications and side effects)	5	4	3	2	1
F17	Counseling approaches for customers who are victims of sexual violence	5	4	3	2	1
F18	Is there any other knowledge that you consider necessary for dispensing oral emergency contraception?					

# What do you find $\underline{\text{difficult}}$ when dispensing emergency oral contraception?

		Difficult	Rather difficult	Neutral	Rather easy	Easy
F19	Dealing with very young customers (under 16 years old)	5	4	3	2	1
F20	Dealing with customers who are victims of sexual violence	5	4	3	2	1
F21	Dealing with customers who repeatedly request emergency oral contraception	5	4	3	2	1
F22	Dealing with the partner of the customer	5	4	3	2	1
F23	Time burden for the pharmacist due to conducting the consultations	5	4	3	2	1
F24	Is there anything else you find difficult when dispensing oral emergency contraception?					

# About the $\underline{\text{future dispensing}}$ of emergency oral contraception

What should be done to  $\underline{\text{facilitate access}}$  to emergency oral contraception?

		Agree	Rather agree	Neutral	Rather disagree	Disagree
F25	24-hour on-call service for all pharmacies dispensing oral emergency contraception	5	4	3	2	1
F26	Dispensing free of charge	5	4	3	2	1
F27	Dispensing in advance	5	4	3	2	1
F28	Free OTC dispensing (no consultation) with age restriction (> 18 years)	5	4	3	2	1
F29	Free OTC dispensing (no consultation) without age restriction	5	4	3	2	1
F30	Enabling online sale	5	4	3	2	1
F31	Are there any other measures that you think should be taken to facilitate access?					

ere anything else you would like to share regarding dispensing of emergency oral contraception?

#### Please answer the following questions about yourself.

- F33 What is your gender?
  - 1. Male
- 2. Female
- 3. Other or would prefer not to say
- F34 What is your age?
  - 1. Under 30 years old
  - 2. 30 39 years old
  - 3. 40 49 years old
  - 4. 50 59 years old
  - 5. Over 60 years old
- F35 How long is your work experience as a pharmacist?
  - 1. Less than 5 years
  - 2. 5-9 years
  - 3. 10-19 years
  - 4. 20-29 years
  - 5. More than 30 years
- F36 What days of the week is your pharmacy open? (multiple answers)
  - 1. Monday
  - 2. Tuesday
  - 3. Wednesday
  - 4. Thursday
  - 5. Friday
  - 6. Saturday
  - 7. Sunday