ISSN 1592-1638 (print) - ISSN 2531-4122 (on line)

2026 • Vol. 28

Heroin Addiction and Related Clinical Problems

Periodico bimestrale - Sped. in Abb. Post. - D.L. 353/2003 conv. in L. 27/02/2004 n° 46 art. 1, comma 1, DCB PISA - Aut. trib. di Pisa n.5 del 9-3-2000

the official journal of

Europad
European Opiate Addiction Treatment Association
Per aspera ad astra
Since 1994
Affiliated to INTERNATIONAL SOCIETY OF ADDICTION MEDICINE

AU-CNS
Association for the Application of Neuroscientific Knowledge to Social Aims

World Federation for the Treatment of Opioid Dependence
NGO with Special Consultative Status with United Nations Economic and Social Council (ECOSOC)

PACINI EDITORE MEDICINA

AU-CNS PRESS
Contra morem • cum ratione

Association for the Application of Neuroscientific Knowledge to Social Aims
Associazione per l'Utilizzo delle Conoscenze Neuroscientifiche a fini Sociali

Heroin Addiction and Related Clinical Problems

AU-CNS PRESS
Contra morem · *cum ratione*

E-mail: info@aucns.org
Internet:http://www.aucns.org

PACINI EDITORE MEDICINA

E-mail: info@pacinieditore.it
Internet:http:// www.pacinieditore.it

Pacini Editore & AU-CNS

Research Article

Heroin Addict Relat Clin Probl 2026; 28, 16
https://doi.org/10.62401/2531-4122-2026-16

HEROIN ADDICTION & RELATED CLINICAL PROBLEMS
www.europad.org
www.wftod.org

Should off-label prescription of controlled medicines be notified?

Caroline Schmitt-Koopmann [1], Carole-Anne Baud [2], Stéphanie Beuriot [2], Barbara Broers [3], Cheryl Dickson [4], and Olivier Simon [4]

1. *Faculty of Biology and Medicine, University of Lausanne, Switzerland*
2. *Faculty of Business and Economics, University of Lausanne, Switzerland*
3. *Faculty of Medicine, Geneva University Hospitals, Geneva, Switzerland*
4. *Addiction Medicine, Lausanne University Hospital, Lausanne, Switzerland*

Summary

Background: In medical practice off-label prescription of medications, including controlled medicines, is common. Most countries have no legal provision for off-label prescription and use, but in Switzerland physicians are required to notify local health officials when they prescribe narcotic and psychotropic substances off-label. However, an exact definition of what constitutes off-label use is absent in the legal text. The aim of our study was therefore to investigate how this legal requirement is applied in practice. **Methods:** We investigated the definition and history of this provision and performed semi-structured interviews with 42 professionals from Switzerland's local health authorities, on their experience with notifications. This work was undertaken as part of a Swiss National Science Foundation project on the regulation of controlled medicines. **Results:** We found that, even if off-label prescribing is common, officials receive only very few notifications. When they do, their analysis is superficial, sometimes a call for clarification, and archiving done without any action. The officials we interviewed had various definitions for off-label prescription and use as well as different opinions regarding the aims and usefulness of this legal requirement. **Conclusions:** Based on our findings and compared to other countries, we recommend that the federal legislator re-evaluates the necessity of obligatory notification for off-label prescription of controlled medications, in Switzerland.

Key Words: Off-label, Narcotics, Psychotropics, Regulation, Switzerland

1. Introduction

Off-label prescription occurs when a physician prescribes a medication in a manner not foreseen by the professional product information approved by the national medicines agency [1]. It can be perceived as a relatively simple concept, yet there are divergences in its regulation and definition **[6]**.

Off-label prescribing is a common practice in medicine across disciplines. It is especially abundant in paediatrics, as this population is (still) often excluded from initial clinical trials **[4]**. In order to address unmet clinical needs, in palliative care a high prevalence of off-label use is found **[2]**.

In a European Union (EU) report on various adult populations in inpatient settings (23 studies, covering data from 6 member states) it was shown that between 7% and 95% of the prescriptions investigated were off-label. In outpatient settings (13 studies, covering data from 6 member states) a range of 6% to 72% was found [2]. A 2015 report by the Swiss government estimated that between 20% and 60% of prescriptions are off-label [3]. Furthermore, the trade association of Swiss illness-funds, Santésuisse, estimates that insurances review 25'000 requests annually for reimbursement of medicines that are prescribed off-label [4].

Corresponding author: Dickson, Cheryl, Addiction Medicine, Lausanne University Hospital , CH-1011 Lausanne, Switzerland.
Phone: +41-21-314-92-07; E-mail: cheryl.dickson@chuv.ch

At an international level, there is an ongoing debate about whether, and how, to regulate off-label use of medicines. The FDA supports off-label use; as long as the medicine is legally approved for at least one therapeutic indication and the prescriber is well-informed about the product **[3]**. Similarly, according to the mentioned European report (for details see endnote [2]), 11 out of 21 investigated EU member states have no specific policy tools on off-label use; the reasoning is that off-label use should be dealt with at the prescriber level, rather than at the regulatory or healthcare system level. Prior informed consent should be the rule.

In contrast, the European report details that the remaining ten EU member states have taken measures to control off-label prescribing, for example, by issuing specific legislation to create a regulatory framework. France has a legal framework where a relevant agency issues a temporary recommendation for use (formerly recommandations temporaires d'utilisation; RTU, today Autorisation d'Accès Compassionnel; AAC), thereby approving specific off-label use **[3]**. The Dutch authorities require that the relevant professional body develops protocols or professional standards regarding the specific off-label use (see endnote 2).

In Switzerland, off-label prescription and use of non-controlled medicines is not prohibited and does not require notification. If a Swiss physician prescribes a medicine off-label, the person must be informed of the associated risks and consequences and provide informed consent. The consent needs not be written in the patient file (according to Kantonsapothekervereinigung, see endnote 1).

Still, as specified in Art. 11 para. 1bis Federal Narcotics Act (NarcA), "physicians and veterinary surgeons who dispense narcotics authorized as medicinal products for indications other than those for which they were authorized must report this within 30 days to the relevant cantonal authorities". Furthermore, "They must provide all the information requested by the relevant cantonal authorities on the nature and purpose of the treatment."[5]. To our knowledge, Switzerland is the only country with a legal provision specifically for the off-label use of controlled medicines.

Although there are no specific figures available on the number of controlled medicines (i.e., medicines that are scheduled as narcotic or psychotropic substances) prescribed off-label, it is reasonable to assume that it is not uncommon. For example, for attention deficit hyperactivity disorder, methylphenidate (Ritalin®) is only approved for persons under the age of 18, yet it is often also prescribed to adults **[5]**. Also, benzodiazepines and z-drugs are often prescribed at higher doses or quantities and for a longer duration than their authorization allows officially [6].

1.1. An unclear definition

In Switzerland, neither the Therapeutic Products Act nor the Narcotics Act (NarcA) [7] define off-label use. Even Art. 11 para. 1bis NarcA, cited above, does not impose a narrow or broad definition. In the narrow sense, off-label refers to prescribing for a different therapeutic indication than what is admitted in the marketing authorization. In a broad sense, off-label use encompasses all deviations from the approved professional use information, such as use at a greater or lower dosage, for a longer or shorter period than authorized, or in other treated populations.

A broad definition is suggested by the Federal Narcotics Control Ordinance, who indicate which information cantonal authorities must receive. The notification must contain the name, quantity, dosage, and indication of the controlled medication that is prescribed off-label [8]. However, the length of treatment is not included. The Swiss Academy of Medical Sciences (SAMW) and the Association of Cantonal Pharmacists have also chosen and published a broad definition of off-label use [9].

On the other hand, the debates surrounding the adoption of the NarcA suggest that a narrower interpretation is warranted. Indeed, the initial version of the article, proposed by the National Council's Committee on Social Security and Public Health, clearly specified a broad definition [10]. But in the consultation procedure, many stakeholders criticized this broad definition. Eight cantons (out of 26) recommended the deletion of the article, arguing that it would entail considerable additional effort for the physicians and the responsible cantonal authorities without improving safety [11]. Four cantons questioned the measure's usefulness, and three commented that the concrete implications for cantonal and federal authorities would be unclear **[8]** (also see endnotes 10 and 11). After the consultation, the article was modified and shortened to the current version.

The difference between the French and the German version of Article 11 para. 1bis creates further confusion. The French version states "indication autre que celle qui est admise". The word "admise" (admitted), as opposed to authorized, suggests that a given treatment may be admitted by current scientific knowledge (and therefore not be off-label), even though Swissmedic, the federal authority which regulates therapeutic products, has not authorized it. In the German version, the word "zugelassene" refers to an indication "approved" by Swissmedic.

1.2. Aims

This article is part of a research project that analyzed how the regulation of controlled medicines is implemented in Switzerland. Other topics

in the associated questionnaire have been published elsewhere [7, 8]. In this sub-study, we investigated how the responsible health officials (cantonal physicians and cantonal pharmacists) apply the legal requirement pertaining to off-label notifications. Based on the literature, we formulated the following hypotheses:

1. Since off-label prescribing is common and notification has been mandatory for almost ten years, we expect the cantons to receive many notifications.
2. Therefore, we expect that the cantons have set up well-defined processes to handle the notifications received.
3. Finally, we expect variation in the definition of what constitutes off-label use. Particularly, since Switzerland is a federalist country with 26 cantons (similar to US states) primarily responsible for public health. Diverse cantonal implementations of federal laws are therefore common.

2. Methods

2.1. Design of the study

We interviewed 42 professionals from Switzerland's local health authorities (cantonal physicians and cantonal pharmacists) about the implementation of the Narcotics Act at cantonal level. The interviews were conducted between 2020 and 2022, as part of a Swiss National Science Foundation – project on the regulation of controlled substances and controlled medicines (grant number 182477).

The questionnaire included questions on all the cantonal authorities' tasks relating to the Narcotic Act since its entry into force in 2011. Indeed, the cantonal physicians and cantonal pharmacists execute a number of different tasks attributed to them by the federal and cantonal legislation.

This article focuses specifically on the authorities' responses concerning the implementation of Art. 11 para. 1bis of the Narcotic Act on the obligation for physicians to notify the cantonal authorities of off-label prescriptions for controlled medicines. Other topics covered in the questionnaire have been published elsewhere [7, 8].

2.2. Sample

The interview sample included 24 cantonal physicians (24 transcripts; 1 cantonal physician is responsible for 2 different cantons) and 17 cantonal pharmacists (17 transcripts; 2 cantonal pharmacists are responsible for 2 different cantons and 1 cantonal pharmacist is responsible for 5 different cantons) and 1 official from Heilmittelkontrolle Zürich (1 transcript) in all Switzerland. We excluded Appenzell-Innerrhoden, as it is very small and the cantonal physician was not available to take part in the study.

2.3. Procedure

The preparation and interview technique has been described in two other published (open access) articles [7, 8] under the same research protocol, which had been approved by the research ethics committee of the University of Lausanne (Commission d'éthique de la recherche) [7]. The research protocol and the transcripts of the interviews are published on the SWISSUbase catalogue (ref. no 20733; access on request).

2.4. Data analysis

The interviews were analyzed using an analytical framework approach with qualitative content analysis as described [7].

3. Results

3.1. Number of notifications

Officials in five cantons reported receiving no notifications per year, in three other cantons less than ten, in five cantons between 10 and 20, and in one canton 30. A total of 11 cantons did not provide any information (see **Figure 1**).

The cantons that do receive notifications state that the number received is nowhere close to what would be expected if the provision was obeyed, knowing the prevalence of off-label prescribing (see pt. 4). Officials responsible for 11 cantons believe that physicians do not deliberately omit to notify but are unaware of the legal requirements. One cantonal authority thought that physicians might be purposefully ignoring their obligation. It must be noted that cantonal officials have no way of knowing whether a physician is compliant with the requirement.

Officials from 4 cantons mentioned that notification is sometimes sent by pharmacists, even though the latter are not bound by Article 11 para. 1bis NarcA, primarily when concerned about excessively high doses being prescribed.

3.2. Established procedures

Out of the 25 cantons included, 13 have specific declaration forms, usually on the website of the cantonal health authority, to be used by physicians submitting off-label notifications (see **Figure 1**). The forms are similar, asking for the information listed in the Narcotics Control Ordinance (see endnote 12). Nevertheless, one cantonal form requires the persons' initials and year of birth (Basel-Landschaft), and an-

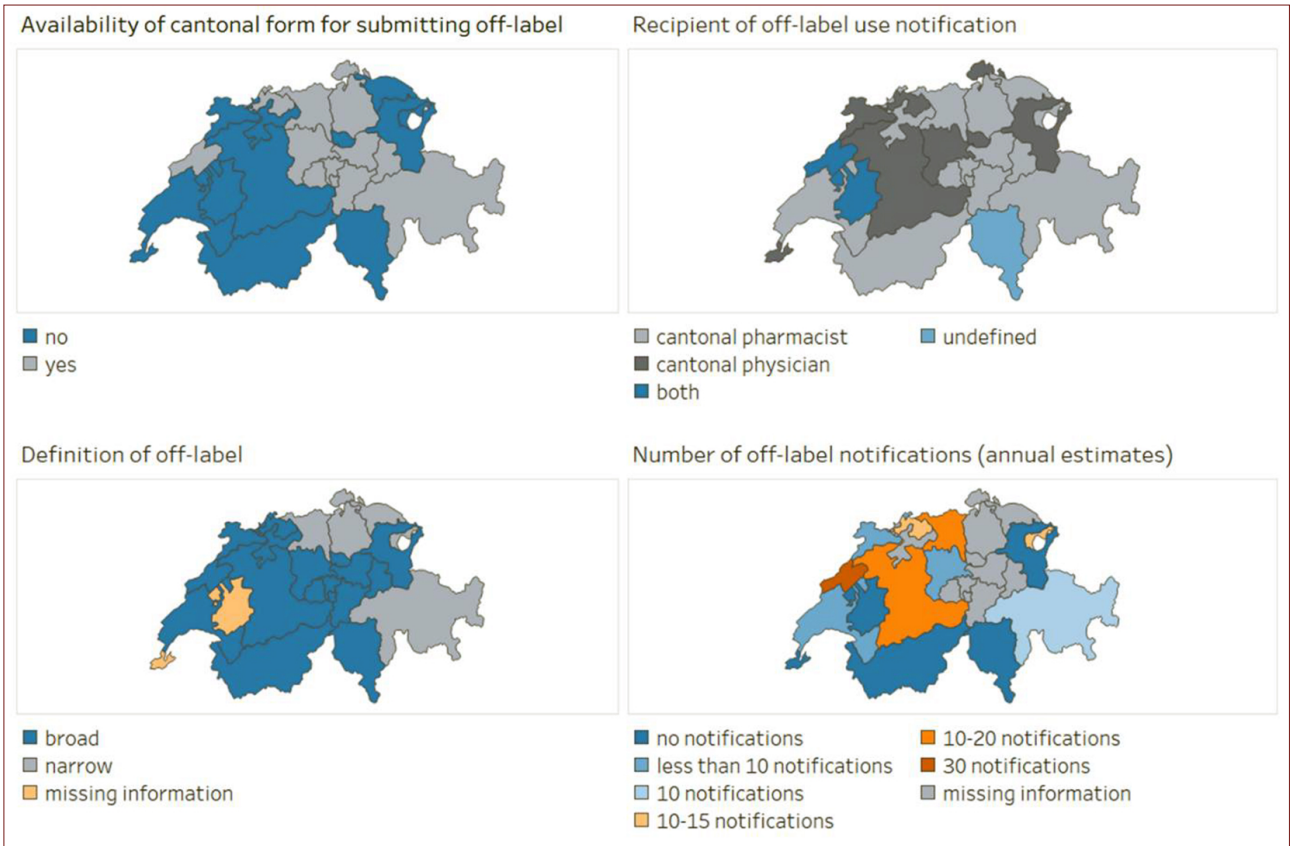

Figure 1. Overview of the cantonal implementation of off-label notifications of controlled medicines. Information is based on the conducted interviews

other is more similar to an opioid agonist treatment (OAT – art. 3e NarcA) authorization, requiring complete personal data (Neuchâtel). The other 12 cantons do not offer a form on their website and do not provide guidance as to how, when and to whom notifications should be submitted.

Cantons can choose which services are to receive off-label use notifications. In 15 cantons, this task has been assigned to the cantonal pharmacists (see **Figure 1**). In eight cantons, the cantonal physicians receive off-label notifications. In three cantons, it was not stated who should receive the notifications. Sometimes, it is the cantonal law that specifies this responsibility; sometimes it derives from an unofficial practice.

Officials from 13 cantons said they do nothing with the received notifications and just archive them. The others examine them to investigate possible problems (e.g., excessive dosage) and sometimes contact the prescribing physician to have a telephone discussion. Officials from two cantons explicitly said they acknowledge receipt of the notifications to the submitting physician, before archiving the notifications. Notifications are nowhere analyzed collectively as a dataset.

3.3. Differences in definition

Six cantons, all from the Swiss German-speaking part, have chosen the narrow definition, i.e., the notification is only required when the physician prescribes for a different therapeutic indication. In four of these cantons, the narrow definition is also clearly stated on the forms, except in Appenzell-Ausserrhoden and Thurgau, which have no form.

Through our interviews, we learned that 17 cantons had adopted a broad definition of "off-label" prescription (**Figure 1**). However, this is not articulated in any official document. As a reminder, in 12 cantons, there were no official forms used. In two cantons, we did not obtain information about the used definition of off-label prescription.

3.4. General opinions

We asked the officials what they thought was the purpose of the off-label notification requirement and whether they considered it useful in that regard. 12 officials criticized the NarcA requirement for not having a clear purpose. They also regretted the uncertainty as to how the notifications should be processed. Lack of purpose is cited as one of the reasons why officials do not enforce the provision. Neverthe-

less, two participants said the data could be interesting if comprehensive.

Regarding the intended purpose, two participants hypothesized that the legislators wanted to control physicians' prescribing patterns, primarily by discouraging them from prescribing controlled medicines. Through this requirement, physicians would be brought to rethink whether off-label was truly necessary.

One participant hypothesized that the provision could be useful for later extending the label, meaning the product information could then be amended. For example, a new indication or another treatment group could be included.

Two officials mentioned the enhancement of safety, as a purpose underlying the provision.

Two participants emphasized that off-label prescription should remain the responsibility of the physician. One participant stated that Art.11 para. 1bis NarcA sets forth a duty and hence must be obeyed, four participants expressed that they have other priorities and 11 participants said that they would be happy to remove the requirement. They recognized that if physicians were to start to comply, they would not have the resources to handle the ensuing notifications. One participant pointed out that other tools are more suitable for identifying physicians who overprescribe, such as the Swissmedic narcotics bookkeeping system, then known as MESA (renamed in 2026 as NDS WEB2). However this tool only identifies extreme overprescription.

Finally, none of the officials interviewed mentioned the sanctions (custodial sentence not exceeding three years or a monetary penalty) associated with non-compliance (according to art. 21 NarCA; cited in Endnote 7).

4. Discussion

Even though off-label prescription of controlled medicines is common, our data reveal that in the Swiss context, where these prescriptions should be notified to cantonal authorities, the cantons receive very few notifications. We thus reject our first hypothesis (i.e., that cantons receive many notifications). This is probably linked to the fact that cantonal officials question the value of the requirement, are unsure about its purpose and fail to see its benefits. Indeed, the authorities do not have access to the medical record; it is challenging for them to determine whether off-label is justified or not. Also, cantonal pharmacists and cantonal physicians are not necessarily expert pharmacologists. Hence, they have not implemented processes to encourage notification nor to handle and process notifications. Our second hypothesis (that cantons will have well-defined processes to handle notifications) is therefore also incorrect. Lastly, six German-speaking cantons have adopted a narrow definition of off-label use, while the majority (18 cantons) chose a broad definition. Our third hypothesis (that there will be variation in the definition) is therefore correct.

4.1. Uncertainty is the main issue

The unclear definition of off-label prescription creates uncertainty for the physicians. For example, a physician may have legitimate doubts as to whether a long-time prescription of benzodiazepines requires notification. Given their limited resources, the uncertainty at the level of the cantonal authorities results in them not enforcing the provision and not informing the physicians. One method of the cantonal authorities to cope with the uncertainty might be to create their own definitions. However, it is unclear how much room for manoeuvre they have.

With regard to sanctions, Art. 21 NarcA states that any person who fails to notify off-label use on purpose is liable to a custodial sentence not exceeding three years or a monetary penalty **[1]**. Negligence is punished by a monetary penalty. However, none of the officials interviewed mentioned sanctions associated with non-compliance. We are aware of only one legal case in which a physician was sanctioned for not having notified an off-label use of controlled medicines but in this specific case there were a number of other infractions (Federal court, case no 2C_782/2020, May 26, 2021). So, given the ambiguous definition of off-label use, it appears highly unlikely that a physician would be sanctioned if he did not notify, as a clear and precise law is required to inflict criminal sanctions (Art. 1 Criminal Code).

4.2. Public interest and proportionality

In Switzerland, state activities that limit fundamental liberties, including economic freedom, must be anchored in a provision of a statute; the rule must pursue a public interest and use measures proportionate to the objective (Art. 5 para. 2 Swiss constitution). When Art.11 para.1bis NarcA was adopted, the government explained its purpose as follows: to "control prescribing by health professionals in areas where recognized medical rules are still lacking to avoid abuses" and to "obtain further information and to clarify the corresponding risks" (for details of the report see endnote x). We can distinguish four interconnected objectives: (1) to limit prescribing, which might not be based on recognized medical rules; (2) to avoid non-medical uses; (3) to gather information; and (4) to use this information to minimize risks. However, these objectives cannot be measured. The true aim remains vague, as it is not defined what exactly is "abuse" or "risk". In any case, the objectives are not attained in the current notification system be-

cause the notifications alone do not allow the cantonal officials to identify inappropriate prescribing. As some cantonal officials pointed out, it is impossible, based on the notification alone, to ascertain whether an off-label prescription is warranted; this would require access to the medical record. For the same reasons, the authorities cannot assess the risks involved. Furthermore, they have very limited authority to influence the prescriptions and would incur a legal risk if they were to dictate a medical course of action.

Having 26 recipients of these notifications goes against the objective of gathering information and using it to minimize risks. In the current system, the notifications are not aggregated to generate datasets, which could then be analyzed to improve medical best practices and issue guidelines. Nor is there a feedback loop to Swissmedic to amend the information for professionals.

In summary, the public interest remains vague, and the current notification system is unsuitable to attain the aims stated in the preparatory work by the federal legislators **[1]**.

4.3. International comparison

Compared to other European countries, only the Swiss legislature has deemed it necessary to regulate the off-label use of medicines that fall under the NarcA. Possibly, they considered that controlled medicines were more dangerous than "regular" ones, with the risk of diversion for non-medical purposes. Yet, to our knowledge, no other European countries have implemented similar regulations based on the argument that off-label use of controlled medicines would be more dangerous.

The four objectives mentioned above are different in their nature. On the one hand, limiting prescribing and preventing non-medical use implies a restrictive approach. These objectives align well with the Dutch system, which only allows off-label prescribing based on protocols or professional standards. On the other hand, gathering information and using it to minimize risks encourages exploration. The French system, which is geared towards amending the professional information, seems more suitable for gathering information and reducing risks (see endnote 2).

Without choosing between a clearly restrictive or explorative purpose, the implementation is bound to be different. For the first, an approval system with, for example, a validation through a second medical opinion, would be appropriate. For the latter, a database would need to be established to collect data and use it to evolve current medical clinical recommendations.

4.4. Limitations

Our study has several limitations. It compares data from all of Switzerland, with the exception of one small canton. However, it does not integrate the perspectives of the prescribers, pharmacists, legislators, or federal authorities. Finally, some data are missing because the cantonal authorities were unable to provide them (e.g. number of notifications).

4.5. Recommendations

The Swiss model of obligatory notification of off-label prescription of controlled substances is unique, but we recommend the Swiss legislator to evaluate whether (and why) the obligation is still necessary. In our view, the provision can be removed for the three following reasons: it has not really been applied in the last ten years; no problems seem to arise from the lack of implementation, and the responsible cantonal authorities see little value in it. In addition, we recommend that cantonal authorities transparently inform on their websites how off-label use of controlled medicines should be handled in their canton.

Lastly, physicians must absolutely be aware that if they prescribe off-label, they carry the responsibility to inform their patient about potential risks, and about (non) reimbursement issues. Therefore, they must document in the medical records how they informed the person and why they chose to prescribe off-label. If they are not sure, they should reach out and ask for a second medical opinion. Professional associations should be encouraged to provide protocols or professional standards, and continuous training.

Other countries could learn from the points to be addressed in the Swiss system and ensure a clear purpose and definition when attempting to regulate off-label use, and the need to clearly inform prescribing physicians of legal provisions.

5. Conclusions

Our study highlights the unclear definition and objectives of the Swiss notification requirements for off-label prescription of controlled medicines. This ambiguity leads to few notifications from the physicians and – correlatively – low interest in receiving them from the cantonal authorities. The almost non-existent compliance with this requirement does not seem to have given rise to any major safety problems. Therefore, we recommend the federal legislator to re-evaluate the necessity of the provision.

References

1. Baud C. A., Junod V., Broers B., Schmitt-Koopmann C., Simon O. (2022): Deux arrêts du Tribunal fédéral

sur la prescription « off-label » de stupéfiants et psychotropes. *Life Sci Recht* (2): 69.
2. Hagemann V., Bausewein C., Rémi C. (2021): Off-label use in Palliative Care – more common than expected. A retrospective chart review. *Eur J Hosp Pharm*: 2021.
3. Lenk C., Duttge G. (2014): Ethical and legal framework and regulation for off-label use: European perspective. *Ther Clin Risk Manag.* 12(10): – 546.
4. Meng M., Lv M., Wang M., Yang B., Jiao P., Lei W., Lan H., Shen Q., Luo X., Zhou Q., Yu X. (2022): Off-label use of drugs in pediatrics: a scoping review. *Eur J Pediatr*. 181(9): 3259-3269.
5. Petitjean S., Ladewig D., Meier C. R., Amrein R., Wiesbeck G. A. (2007): Benzodiazepine prescribing to the Swiss adult population: results from a national survey of community pharmacies. *Int Clin Psychopharmacol*. 22(5): 292-298.
6. Rusz C. M., Osz B. E., Jitca G., Miklos A., Batrinu M. G., Imre S. (2020). Off-Label Medication: From a Simple Concept to Complex Practical Aspects. *Int J Environ Res Public Health.* 18(19): 10447.
7. Schmitt-Koopmann C., Baud C.-A., Beuriot S., Junod V., Broers B., Simon O. (2024): Cantonal opioid agonist treatment authorisation systems – a mixed-method qualitative investigation. *Swiss Med Wkly.* 154(6): 3629.
8. Schmitt-Koopmann C., Baud C.-A., Junod V., Simon O. (2021): Switzerland's Narcotics Regulation Jungle: Off-Label Use, Counterfoil Prescriptions, and Opioid Agonist Therapy in the French-Speaking Cantons. Int *J Environ Res Public Health*. 18(24): 13164.

Contributors

CS-K, C-AB and OS were involved in the study design. CS-K, C-AB, SB and OS were responsible for the investigation and analysis. All authors had full access to the survey data critically reviewed the manuscript and had full control, including final responsibility for the decision to submit the paper for publication.

Role of the funding source

This study was part of a project entitled "Regulation of controlled medicines in Switzerland", funded by the Swiss National Science Foundation), grant number 182477.

Conflict of interest

Authors declared no conflict of interest.

Ethics

Not applicable.

Endnotes

[1] According to governmental documentation, such as: Kantonsapothekervereinigung. Positionspapier 0007 V02 Empfehlungen zum Off label use von Arzneimitteln. Available from: https://www.kantonsapotheker.ch/fileadmin/docs/public/kav/2_Leitlinien__Positionspapiere/0007_anforderungen_an_den_off-label-use.pdf; and Commissioner O of the. FDA. FDA; 2019. Understanding Unapproved Use of Approved Drugs 'Off Label'. Available from: https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label"

[2] For further details see the following report: Weda M, Hoebert J, Vervloet M, Moltó Puigmarti C, Damen N, Marchange S, et al. Study on off-label use of medicinal products in the European Union. Available from: https://op.europa.eu/en/publication-detail/-/publication/ecf85518-d376-11e9-b4bf-01aa75ed71a1

[3] Details of the report are as follows: Bundesrat. "Heilversuche" Bericht in Erfüllung der Motion 11.3001 der Kommission für Wissenschaft, Bildung und Kultur des Nationalrates. 2015. p. 29. Available from: https://www.parlament.ch/centers/eparl/curia/2011/20113001/bericht%201.1%20br%20d.pdf

[4] As detailed in the following report by santésuisse: "Off-Label" muss die Ausnahme bleiben! - santésuisse - Die Schweizer Krankenversicherer Available from: https://www.santesuisse.ch/details?backLinkPid=66&cHash=148a82cf845f5667014d42458e5b3913

[5] The document referred to is: LU - Merkblatt Bewilligungs und Meldepflicht Betäubungsmittel / Off-label. Available from: https://gesundheit.lu.ch/-/media/Gesundheit/Dokumente/Bewilligungen_und_Merkblaetter/Merkblatt/Merkblatt_Bewilligungs_und_Meldepflicht_Betaeubungsmittel.pdf

[6] Legal requirements are specified in: SR 812.21 - Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA). Available from: https://www.fedlex.admin.ch/eli/cc/2001/422/en

[7] The 2 acts are as follows: SR 812.121 - Federal Act of 3 October 1951 on Narcotics and Psychotropic Substances (Narcotics Act, NarcA). Available from: https://www.fedlex.admin.ch/eli/cc/1952/241_241_245/en

Art. 49 BetmKV . Available from: https://www.fedlex.admin.ch/eli/cc/2011/362/de#art_49

[8] As documented in: Schweizerische Akademie der MedizinischenWissenschaften (SAMW), Verbindung der Schweizer Ärztinnen undÄrzte (FMH). Rechtliche Grundlagen im medizinischen Alltag. Ein Leitfaden für die Praxis. 2020; Available from: https://zenodo.org/record/3635309

[9] Documents demonstrating this include: Swiss Academy of Medical Sciences (SAMW). Abgrenzung von Standardtherapie und experimenteller Therapie im Einzelfall. 2014; and Kommission für soziale Sicherheit und Gesundheit des Nationalrates. Bericht zur Parlamentarische Initiative Teilrevision des Betäubungsmittelgesetzes (05.470) 2006.p. 8609. Available from: https://fedlex.data.admin.ch/filestore/fedlex.data.admin.ch/eli/fga/2006/1086/de/pdf-a/fedlex-data-admin-ch-eli-fga-2006-1086-de-pdf-a.pdf

[10] For details see: Bundesamt für Gesundheit. Bericht über die Ergebnisse des Anhörungsverfahrens betreffend die Bundesrats-Verordnungen im Betäubungsmittelrecht (Vernehmlassung 2008/77). 2011. p. 5, 18, 19, 25. Available from: https://fedlex.data.admin.ch/filestore/fedlex.data.admin.ch/eli/dl/proj/6008/77/cons_1/doc_8/de/pdf-a/fedlex-data-admin-ch-eli-dl-proj-6008-77-cons_1-doc_8-de-pdf-a.pdf

[11] The relevant report is: Bundesrat. Botschaft über die Änderung des Betäubungsmittelgesetzes vom 9. März 2001. Bundesblatt. 2001 Mar 9;(01.024):3770–1.

[12] Details of this ordonnance are: SR 812.121.1 - Verordnung vom 25. Mai 2011 über die Betäubungsmittelkontrolle (Betäubungsmittelkontrollverordnung, BetmKV). Available from: https://www.admin.ch/opc/de/classified-compilation/20101221/index.html

Received Mount June 2, 2026 – Published July 3, 2026