

# Federal Act on Medicinal Products and Medical Devices

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## COMMENTARY ON

# Art. 64a TPA

A commentary by Remus Muresan

### SUGGESTED CITATION

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### **Art. 64a Cross-border inspections**

<sup>1</sup> Competent foreign authorities shall, on notifying the Agency, be entitled to inspect Swiss establishments operating in the therapeutic products sector provided that:

- a. the inspection has the sole purpose of verifying compliance with regulations on therapeutic products;
- b. the results of the inspection are used solely in administrative proceedings in connection with the enforcement of regulations on therapeutic products;
- c. the establishment concerned consents to the inspection; and
- d. the foreign authority informs the Agency of the results by providing it with the inspection report in an official Swiss language or in English.

<sup>2</sup> The Agency may accompany the foreign authority during its inspection.

<sup>3</sup> It may in consultation with the competent authorities carry out inspections of establishments abroad that operate in the therapeutic products sector, if this is required to guarantee the protection of health. In addition, it may participate in inspections carried out by competent foreign authorities.

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## I. THE PRACTICAL AND LEGAL CONTEXT OF ART. 64A

### A. The Practice of “Cross-Border Inspections” in the Field of Medicinal Products

- 1 Unlike regulations in many other economic or product sectors, pharmaceutical law establishes not only **requirements and standards** pertaining to the products themselves, but also those **directed at the respective manufacturers and other economic actors**. For example, pursuant to Art. 7(1), medicinal products and pharmaceutical excipients must be manufactured in accordance with the “recognized rules of Good Manufacturing Practice.” Anyone engaged in the wholesale trade of medicinal products, for instance, must comply with the “recognized rules of Good Distribution Practice” (para. 29). And manufacturers of medical devices must meet numerous requirements—particularly regarding organization, documentation, and quality management (Art. 47a et seq.; Art. 47 et seq. MedDO; Art. 50 MedDO in conjunction with Art. 10 EU-MDR).
- 2 Compliance with these requirements by economic operators is verified, not least through **inspections** of the operators conducted by the respective competent authorities **on-site**. The basis for such inspections (or “inspections”) is provided, for example, by Art. 6 para. 2 (for manufacturers of medicinal products), Art. 28(4) (for pharmaceutical wholesalers), or Art. 77 MedDO (for economic operators who manufacture or handle products within the meaning of the MedDO).
- 3 The circumstances described above apply exclusively to purely Swiss situations. However, the activities of (for example) manufacturers of medicinal products based in Switzerland are not generally limited to this country; rather, the manufactured **products are very frequently exported to other countries**. Conversely, numerous products that qualify as medicinal products within the meaning of the TPA are produced by manufacturers based abroad and imported into Switzerland.
- 4 This international interdependence has led—at least between certain countries—to the establishment of a **practice of conducting inspections of manufacturers and other economic operators abroad as well**. That is to say, that government authorities responsible for inspecting economic actors

under their respective national laws do not only inspect those actors based domestically, but also those based abroad who export or intend to export their products to the relevant country. The number of such inspections is steadily increasing. However, these raise various legal questions, particularly regarding international law. For example, the admissibility of an “extraterritorial” application of manufacturer obligations prescribed by national law to foreign economic operators may already appear questionable. However, on-site inspections of economic operators by authorities of another state (“cross-border inspections”) present themselves as (potentially) particularly problematic.

## B. Aspects of “cross-border inspections” under international law

Representatives of medicinal product authorities are generally to be classified 5 as *organs* of the respective states within the meaning of international law; their actions are therefore attributable to those states. The on-site inspections of manufacturers and other economic operators by members of a foreign authority are thus an official act of one state on the territory of another state. Such acts consequently constitute violations of the territorial sovereignty of the affected state (as an aspect of its sovereignty) by another state; they are therefore **in principle contrary to international law** and entail international legal responsibility on the part of the acting State.

However, the **contravention of international law does not apply**, in particular, 6 if the affected State consents to the performance of the act in question, i.e., agrees to it. Such consents may also be subject to certain prerequisites or conditions; if these are not met, the act in question remains contrary to international law. For the consent to be valid, it must also be granted by a state organ that is “not manifestly incompetent.”

## C. Criminal Law Protection of Territorial Sovereignty Guaranteed under International Law

Swiss law provides for specific criminal law protection of the territorial 7 sovereignty of states—which, as outlined above, is fundamentally guaranteed and protected under international law—namely, both that of Switzerland and that of other states. As far as the territorial sovereignty of *Switzerland* is concerned, **Art. 271 no. 1 SCC** criminalizes acts that “fall within the remit of an authority or a public official” and are carried out on Swiss territory on behalf of a foreign state without having obtained a “permit” to do so. On-site inspec-

tions by foreign medicinal products authorities in Switzerland clearly fall under the acts covered by Art. 271 no. 1 of the SCC. They are therefore punishable if no “authorization” has been obtained or if, although an “authorization” has been obtained, the conditions or requirements associated with it are not complied with. The “authorization” within the meaning of Art. 271 no. 1 SCC may be a case-by-case or a general authorization. *Generally*, the acts in question may be declared permissible, in particular, by law or in bilateral or multilateral international agreements. To the extent that an act on foreign territory is covered by the consent or approval of the state concerned, which already negates its *violation of international law* (see above N. 6), an “authorization” within the meaning of Art. 271 no. 1 SCC is generally also deemed to exist, leading to the non-punishability of the conduct in question. However, these two elements are not entirely identical; in particular, the act’s contravention of international law is *not* a prerequisite for criminal liability under Art. 271 no. 1 SCC.

- 8 All in all, it is therefore certainly possible—at least in theory—that, for example, inspectors from the U.S. Food and Drug Administration (FDA) could be arrested in Switzerland after conducting an unlawful on-site inspection and charged and convicted under Art. 271 SCC (unless they enjoy immunity from prosecution, which, however, is unlikely to be the case). In this context, it should be noted in particular that any **consent from the inspected company is irrelevant**; that is, as long as there is no government “authorization,” the inspection remains a criminal offense, even if the company in question has consented to it. In practice, however, it is likely to occur only under highly exceptional circumstances that inspectors from foreign medicinal products authorities are actually arrested and prosecuted in Switzerland, even if the inspections they conducted were not (fully) in accordance with legal requirements. Unlawful inspections in the field of medicinal products are generally likely to be (at least initially) be addressed at the diplomatic level or between the relevant specialized authorities.
- 9 As for the territorial sovereignty of states other than Switzerland, **Art. 299 no. 1 of the SCC** makes it a criminal offense to violate the territorial sovereignty of a foreign state, “in particular by performing official acts without authorization on the territory of that foreign state”. An official act is unauthorized if—in this regard, Art. 299(1) SCC is interpreted in conjunction with Art. 271(1) SCC—no “authorization.” Thus, if, for example, representatives of Swissmedic

conduct on-site inspections of pharmaceutical manufacturers abroad without valid consent to the inspections from the state concerned, the Swissmedic inspectors involved may be prosecuted and convicted in Switzerland under Art. 299 no. 1 of the SCC. In this context, it should be noted that Art. 64a para. 3 does not mean that inspections abroad are automatically deemed permissible within the meaning of Art. 299 no. 1 of the SCC.

With regard to both Art. 271 no. 1 of the SCC and Art. 299 no. 1 of the SCC, 10 “inspections” or official acts that constitute inspections and are carried out **via videoconference** —i.e., without the representative of the authority physically entering the territory of the other state—may also be problematic in light of the aforementioned provisions.

Also with regard to both provisions, it should be noted that, in addition to the 11 objective elements of the offense described above, the subjective element (intent) must be fulfilled, and there must be no grounds for justification or exclusion of culpability. Furthermore, the offenses defined by Art. 271 no. 1 SCC and Art. 299 no. 1 SCC are public offenses; consequently, no criminal complaint is required for their prosecution. The penalties are also identical in principle (imprisonment for up to three years or a fine). Only in the case of Art. 271 no. 1 SCC is it further provided that, in “serious cases,” a prison sentence of not less than one year must be imposed.

## II. ON THE PROVISIONS OF ART. 64A

### A. Background of the Provision

Art. 64a was introduced as part of the revision of the Therapeutic Products 12 Act that entered into force on January 1, 2018, and regulates the “cross-border inspections” that frequently occur in the field of therapeutic products—as already mentioned—, whether by foreign authorities in Switzerland or by Swiss authorities abroad. The provision does not stem from a corresponding proposal by the Federal Council, but rather from an initiative by the preliminary parliamentary committee. In particular, it was intended to regulate the “authorization” required under Art. No. 271 of the SCC, and to create a legal basis clarifying how cross-border inspections are to be organized. The latter, however—given the provision’s considerable need for further specification—has been achieved only to a very limited extent. As for the intended simplification of the “authorization situation,” this has indeed been achieved, since a sepa-

rate official permit is no longer required for every single inspection by a foreign authority in Switzerland. According to the earlier practice—which, although long applied, was purely an *administrative* practice—the State Secretariat for Economic Affairs (SECO) issued the relevant permits after Swissmedic had carried out the necessary preliminary investigations.

- 13 In light of the background outlined above, it is not immediately clear why the provision relevant here—as Art. 64a—was placed in the section of the TPA on “Confidentiality and Data Processing.” Admittedly, a certain, very tenuous connection with the “disclosure of data and information abroad and international administrative assistance” (see the marginal note on the immediately preceding Art. 64; see also N. 36 below). However, there is a far closer substantive relationship to the provision of Art. 60, which concerns the “competence to conduct inspections.” In this respect, it would have made more sense to insert the current Art. 64a into the Therapeutic Products Act as Art. 60a. Ultimately, however, these circumstances merely constitute a “cosmetic flaw” that has no substantive effect.

## B. The Authority of Foreign Authorities to Conduct Inspections in Switzerland (para. 1)

### 1. The Legal Framework

#### a. Overview

- 14 Art. 64a para. 1 establishes the “authority” of “competent foreign authorities” to inspect Swiss companies operating in the medicinal products sector. This authority is subject to compliance with certain requirements specified in the same provision. Accordingly, inspections must be reported to Swissmedic in advance (preamble); they may be conducted solely for the purpose of verifying compliance with medicinal product regulations (lit. a); the results of the inspections may be used exclusively in administrative proceedings related to the enforcement of medicinal product regulations (lit. b); the establishments to be inspected must have given their prior consent to the inspections (lit. c); and the foreign authorities must inform Swissmedic of the results of the inspections (lit. d).

## b. Functions of the Authorization

The authorization pursuant to Art. 64a para. 1 has two functions. On the one 15  
hand, it constitutes Switzerland's **consent** under international law to the conduct of an inspection by representatives of a foreign authority and thus to the performance of an official act by that authority on Swiss territory. And on the other hand, it constitutes the **“authorization” within the meaning of Art. 271 no. 1 of the SCC**, which precludes the criminal liability of the inspection in question—which would otherwise exist in the absence of such “authorization.” Ultimately, the authorization under Art. 64a(1) is the sovereign permission granted by Switzerland, as a subject of international law, to the foreign authority to carry out the specific inspection in question. This permission derives directly from the law. This means that the inspection—provided and as soon as the requirements under Art. 64a(1) are met – may be carried out without further ado; no specific, additional “authorization” or the like is required from a Swiss authority for the specific individual case. However, the authorization under Art. 64a para. 1 – with the exception of Art. 271 no. 1 of the SCC – no effect on any requirements arising from other Swiss regulations; the authorization is not a blanket “clean bill of health.” For example, it does not waive any visa requirements or similar obligations for the foreign inspectors.

## c. Beneficiaries of the authorization

The beneficiaries of the authorization under Art. 64a para. 1 can only be **for- 16  
eign competent authorities**. This implies, first of all, that the body in question must be a *foreign* one. Accordingly, *Swiss* authorities cannot derive any rights—in particular, no powers—from this provision. Furthermore, the requirement that the entity must be an *authority* implies that *private individuals*—or persons acting on behalf of private entities—and their actions are generally excluded. However, private individuals may qualify as beneficiaries under Art. 64a(1) if they are entrusted by an authority with the performance of official acts. Finally, the authority must be *competent* to carry out the inspection or control in question. Whether this applies in a specific case must be assessed on the basis of the relevant *foreign* law. If the authority taking action is not competent to carry out the inspection under the law of its own country, the authorization to carry it out pursuant to Art. 64a para. 1 does not take effect.

#### d. Conditions and Limits of the Authorization

- 17 The authorization under Art. 64a para. 1 becomes effective only if the inspection in question is **notified** to Swissmedic in advance. Swissmedic itself has specified in this regard that the notification must be made at least 30 days in advance. Whether Swissmedic is competent to make such a specification at all may, however, appear questionable. In any case, however, the notification within the meaning of Art. 64a para. 1 is merely a *notification*, i.e., Swissmedic is merely required to take note of the information regarding the inspection; in particular, it has no “authorization” or similar powers with regard to the intended inspection. Should Swissmedic have doubts in an individual case as to whether the foreign authority meets the requirements to be authorized to conduct an inspection pursuant to Art. 64a para. 1, it must inform other Swiss authorities that possess the necessary powers to intervene with regard to the inspection (e.g., FDFA, Border Guard).
- 18 The intended inspections must then relate to “**Swiss establishments.**” This includes not only establishments that have their registered office in Switzerland or are incorporated under Swiss law. In light of the territorial jurisdiction relevant under para. 64a(1), only *the premises, facilities, etc., to be inspected must be located in Switzerland*. Whether the enterprise in question is “Swiss” or “foreign,” however, is irrelevant. Accordingly, authorization under Art. 64a para. 1 is also required if premises located in Switzerland—e.g., a business establishment—of a company headquartered abroad (which in this respect does not constitute an actual “Swiss business”) are to be inspected.
- 19 Furthermore, authorization under Art. 64a para. 1 is effective only if the businesses to be inspected are “**active in the field of medicinal products.**” This raises the question of which law should be used to determine whether this applies in a specific case. It stands to reason that one should first refer to the concept of “therapeutic products” under Swiss law. This covers businesses operating in the field of medicinal products and medical devices within the meaning of the TPA and the MedDO. No particular problems arise if the classification of the products in question under foreign law is identical to that under Swiss law. For example, if the products manufactured by the company to be inspected are classified as medicinal products under both Swiss law and the law of the authority intending to conduct the inspection in Switzerland, the company in question must be classified as “operating in the medicinal products sector” within the meaning of Art. 64a para. 1.

However, problems may arise if the definition of “therapeutic products” (or the terms “medicinal products” and “medical devices” encompassed therein) under Swiss law is *not* entirely identical to the corresponding definition under the law of the foreign authority intending to conduct an inspection in Switzerland pursuant to Art. 64a. For example, it is conceivable that a certain product constitutes merely a dietary supplement or food under Swiss law, but is classified as a medicinal product under foreign law. Consequently, the business to be inspected is not “active in the medicinal products sector” under *Swiss* law; under *foreign* law, however, it is. In such cases, *foreign* law is decisive. Accordingly, the business in question must be classified as “active in the medicinal products sector” within the meaning of Art. 64a(1), and the foreign authority’s right to inspect arises directly from this provision. 20

This ultimately results from an interpretation of Art. 64a(1). In doing so, not only must the methods used for interpreting federal laws be taken into account, but also the principles applicable to the interpretation under international law of unilateral declarations by states. This is because, from the perspective of international law, the authority established in Art. 64a para. 1 constitutes Switzerland’s consent to the performance of official acts on its territory by a foreign authority and thus a unilateral (internationally relevant) legal act. 21

The starting point for interpretation from both perspectives is the wording of the provision. However, this does not lead to a clear conclusion. Therefore, the remaining methods of interpretation must be applied, with systematic and teleological interpretation taking center stage. As regards systematic interpretation first, it must be taken into account that para. (a) and para. (b) of Art. 64a(1) mention “regulations on medicinal products,” which clearly refer to corresponding *foreign* regulations. This suggests that, with regard to the classification of “medicinal products” in the contexts of interest here, foreign law is decisive. As for the teleological interpretation of the term “active in the medicinal products sector” in Art. 64a para. 1, it should be noted that the ultimate purpose of this provision is to facilitate inspections of companies based in Switzerland that *export products abroad*. However, the products in question must meet the requirements applicable in the destination country. In this respect, the relevant *foreign* law is again decisive. Accordingly, the teleological interpretation also shows that, with regard to the classification of “medicinal products” in the contexts at issue here, foreign law is decisive. 22

- 23 However, in cases where the product qualifies as a medicinal product under Swiss law but not under foreign law (i.e., in the scenario opposite to that described in N. 20), the foreign authority has no authority to conduct inspections on the basis of Art. 64a para. 1. For in such circumstances, the issue is not the monitoring of compliance with foreign *medicinal product* regulations. This does not, however, mean that inspections of establishments located in Switzerland by foreign authorities are not possible. Such inspections may well be permissible; however, the foreign authority cannot invoke the authority established in Art. 64a para. 1 in this regard. In such circumstances, it must obtain a case-by-case authorization from the competent Swiss authority, as was customary (also) in the medicinal products sector prior to the entry into force of this provision. The same applies, moreover, in *cases of doubt*, i.e., in cases where the classification of the product in question as a “medicinal product” under foreign law is not clear. With regard to all these scenarios, however, *practice* also plays a significant role. If, for example, Switzerland continues to tolerate inspections on its territory based on Art. 64a(1), even though the inspected establishments cannot be classified as “operating in the medicinal products sector” within the meaning of the above explanations, this may—at least under international law—be interpreted as tacit recognition of a corresponding entitlement. The relevant Swissmedic “Information Sheet,” however, contains no indication that this might be the case.
- 24 The “establishments operating in the field of medicinal products” within the meaning of Art. 64a(1) ultimately encompass not only manufacturers (although these are likely to constitute the majority of the inspected establishments), but all establishments that handle medicinal products. Accordingly, for example, (wholesale) distributors and (specialized) transport companies also fall under this term.
- 25 The authority granted under Art. 64a(1) then extends to **inspecting** these establishments. This includes activities such as requesting information and documents, directly questioning employees, and entering premises, etc. As a general rule, inspections take place on Swiss territory in the physical presence of representatives of the foreign authorities (this is, after all, the core of what Art. 64a aims to achieve). However, actions carried out by foreign authorities without entering Swiss territory (e.g., questioning persons located in Switzerland via videoconference) may also fall under “inspect” within the meaning of this provision.

Furthermore, authorizations based on Art. 64a para. 1 cover only those inspections that *are intended to verify compliance with pharmaceutical regulations (lit. a)*. This passage defines—and limits—the **subject matter of the inspections**, which may be carried out on the basis of such authorizations. Consequently, not *just any* aspects—such as the company’s accounting, its financial statements, its compliance with individual labor law provisions, or the like—may be examined within the scope of such inspections. Rather, each individual inspection activity must be connected to the verification of compliance with requirements arising from the relevant medicinal product regulations. Furthermore, the medicinal product regulations in question must be *relevant*. For example, during inspections of a pharmaceutical manufacturing facility, no requirements arising from regulations on medical devices may be examined (and vice versa). 26

Incidentally, the “medicinal product regulations” referred to in Art. 64a para. 1 lit. a always pertain to the respective *foreign* regulations (including, where applicable, applicable international standards and the like). This follows from the “export-oriented” nature of the provision. Moreover, verifying compliance with requirements arising from *Swiss* medicinal products law is ruled out simply because foreign authorities typically lack the relevant expertise. However, foreign legal systems often do not recognize the concept of “medicinal products.” Therefore, when defining the term “medicinal product regulations,” a connection must (nevertheless) be made to the corresponding Swiss concept insofar as it encompasses *medicinal products* and *medical devices*. *These* terms or concepts are well known in numerous foreign legal systems. The requirement under Art. 64a para. 1 lit. a, according to which the inspection in question must aim to verify compliance with therapeutic product regulations, is therefore to be considered fulfilled if the relevant—foreign—regulations concern medicinal products or medical devices. In this regard, however, the remarks already made above regarding possible scenarios in which these terms are not entirely congruent with the corresponding corresponding Swiss terms. In light of the foregoing, the list of inspection subjects contained in the relevant Swissmedic “Information Sheet”—GMP for medicinal products and transplant products, GCP, pharmacovigilance, medical devices—is not to be regarded as definitive or exhaustive, but is merely illustrative in nature. 27

If an inspection is conducted in an individual case by exercising the authority under Art. 64a(1), but the restriction on the scope of the inspection resulting 28

from subparagraph (a) of this provision is not observed, the inspection (under international) law. This not only results in the relevant state's liability under international law toward Switzerland but also renders the actions taken punishable under Art. 271 of the SCC.

- 29 Pursuant to Art. 64a para. 1 **lit. b**, the result of the inspection may, in the state whose authority conducts the inspection, **be used only in administrative proceedings related to the enforcement of therapeutic product regulations**. As regards the “therapeutic product regulations” in this context, these are again the corresponding *foreign* regulations. In this regard, the comments made regarding the same term used in Art. 64a para. 1 lit. a apply analogously. The restriction to *administrative* proceedings means that the findings obtained in the course of inspections may not, for example, be used in civil or criminal proceedings in the state conducting the inspections—and, in particular, may not be made available to other authorities or even private parties.
- 30 The requirement set forth in Art. 64a para. 1(b) raises particular questions insofar as it is one that only becomes relevant once the inspection in Switzerland has *already been completed* and the foreign inspectors have left the country. Consequently, the criterion in question—unlike the requirements set forth in Art. 64a para. 1( a and c—may, as a matter of fact, already be unmet *prior to* an inspection. Thus, this requirement *cannot* constitute a (so to speak, “factual”) *prerequisite* for being permitted to conduct the inspection. The situation would be different, for example, if Art. 64a para. 1 lit. b had been formulated to require a *prior declaration of commitment* on the part of the inspecting state or its authority to use the results of the inspection exclusively in administrative proceedings related to the enforcement of pharmaceutical regulations. However, this is not the case.
- 31 Regardless, inspections conducted on the basis of Art. 64a para. 1 are, in principle, already in compliance with (international) law and not subject to penalties at the time they are carried out, even if the requirement set forth in Art. 64a para. 1(b) b only comes into effect later. However, if the state conducting the inspection subsequently fails to comply with the requirement to use the results exclusively in administrative proceedings related to the enforcement of pharmaceutical regulations, *retroactively* (under international) *law*. Under such circumstances, the conduct of the persons involved—also retroactively—becomes punishable under Art. 271 no. 1 of the SCC. In practice, however, the latter is unlikely to have any significant consequences, as the foreign in-

spectors are generally no longer present in Switzerland at that point. The violation of international law, on the other hand, can certainly still be “punished,” for example by no longer permitting the state in question to conduct further inspections in Switzerland—either categorically or at least until appropriate redress has been provided for the violation of the condition. Under international law, such an approach constitutes an application of the means of retaliation (which is customary and permissible in cases of breaches of international obligations).

In view of the circumstances outlined above, the requirement set forth in Art. 64a para. 1(b) constitutes, from a legal-technical perspective, a *(resolutive) condition*. Consequently, it is specifically not a condition. The latter follows from the fact that the “authorization” of inspections granted under Art. 64a para. 1 constitutes a unilateral legal act under international law. The unilateral imposition of conditions, however, is only possible if the issuing authority holds a superior—e.g., sovereign—position vis-à-vis the addressees of the legal act. In international relations, however, the principle of the sovereign equality of states applies, so that no such superior position exists here. 32

Pursuant to Art. 64a para. 1 **lit. c, the facility to be inspected must consent to the inspection** in order for an inspection to be carried out on the basis of the authorization established in Art. 64a para. 1. This requirement has been clarified by Swissmedic and others to the effect that consent must be granted *in advance*. Although such prior—and, moreover, *express* – consent is unquestionably the rule in practice, this clarification finds no basis either in the wording of the law or in the legislative materials on Art. 64a. In particular, the provision was not formulated to the effect that the establishment must *have* consented to the inspection. Consequently, it is—at least theoretically—entirely possible that ad hoc consents from the establishment to be inspected are also permissible. 33

The consent requirement set forth in Art. 64a para. 1(c) stems from the fact that neither does the foreign authority have the authority to conduct inspections in Switzerland without the consent—or against the will – of the establishment concerned, nor does Swissmedic or any other Swiss authority have the authority to permit inspections by foreign authorities in Switzerland without the consent of the establishment concerned. However, the establishment to be inspected may *in practice* feel more or less compelled to consent to an inspection, as it would otherwise face disadvantages—which, depending on 34

the circumstances of the individual case, may be significant. Such disadvantages may, for example, consist of certain import restrictions or even bans being imposed in the state intending to conduct the inspection regarding products from a manufacturer based in Switzerland as a result of the refusal to consent.

- 35 This circumstance can lead to a particular tension, namely when consent to the intended inspection would, for example, place the affected company in *conflict with Swiss data protection law or with contractual confidentiality obligations*. The latter may be the case, for instance, if the inspecting (foreign) authorities demand the disclosure of information covered by a confidentiality obligation—such as one contained in a Non-Disclosure Agreement (NDA)—that the company has entered into with suppliers, customers, or other contractual partners. While such contractual provisions often contain standard clauses permitting the disclosure of information, among other things, if the company is obligated to do so by an authority. However, in the circumstances relevant here, the issue concerns *foreign* authorities that have no sovereign powers with respect to Swiss companies, meaning that there is precisely no *obligation* to disclose information to them. Accordingly, the disclosure provisions in NDAs entered into by such companies must be carefully drafted so that the companies concerned do not breach the NDAs (which, depending on the contractual terms, may be subject to, among other things, substantial contractual penalties) when they disclose information to foreign authorities in the context of cross-border inspections.
- 36 As for *data protection law*, the disclosure of information that qualifies as personal data within the meaning of Art. 5 FADP to foreign auditors or inspectors may constitute a *transfer of personal data abroad* (by private parties) within the meaning of Art. 16(1) of the FADP. Such a transfer is permissible only under specific conditions. If these are not observed, or not fully observed, the inspected company or the individuals involved may face serious consequences. The special data protection provisions of the TPA (Art. 62–64) offer no remedy in this regard.
- 37 The company subject to inspection is free to determine the factual *scope of its consent*. In particular, it may limit this to specific aspects. However, in this regard as well, it must be assumed that the business will generally grant its consent in full, as prescribed or required by the foreign authority.

The consent of the business concerned is a prerequisite for the corresponding inspection to be carried out on the basis of Art. 64a para. 1 (see above N. 33). This means that conducting an inspection without the consent of the business concerned remains contrary to international law and results in criminal liability for the persons involved acting on behalf of the foreign authority. In other words, *the consent of the business is a prerequisite for compliance with international law and for the immunity from criminal liability* of inspections carried out pursuant to Art. 64a para. 1. In practice, however, it is unlikely that inspections will take place without the consent of the business concerned. The aforementioned effects of the consent requirement may, however, cease to apply if any restriction on consent imposed by the establishment is disregarded in substantive terms (see N. 37 above) during the course of the inspection. In that case, the inspection (once again) become contrary to international law and result in the foreign inspectors being liable to prosecution. 38

Finally, pursuant to Art. 64a para. 1 **lit. d, the foreign authority must inform Swissmedic of the outcome of the inspection**, specifically by delivering the inspection report in a Swiss official language or in English. This requirement—like the one under Art. 64a para. 1 lit. b—is one that only becomes relevant after the inspection has already been completed, and thus is not a (quasi “constitutive”) prerequisite for the legality of the inspection, but rather a (*resolutive*) condition. With regard to the effects of any failure to meet this requirement on compliance with international law and the criminal liability of the foreign authority representatives involved in specific inspections, the comments made regarding Art. 64a para. 1 lit. b (above N. 31) by analogy. 39

According to the relevant Swissmedic “information sheet,” however, inspections by foreign authorities in Switzerland are “permitted” only if, among other things, the authority in question has “agreed” to send Swissmedic a copy of the inspection report (within ten days of the report’s “adoption”). This wording may suggest that Swissmedic actually interprets the corresponding requirement set forth in Art. 64a para. 1(d) as a genuine *prerequisite* for the legality of inspections to be conducted on the basis of Art. 64a para. 1. With such an interpretation, however, the Institute would exceed its authority. This is because it would result in a change to the fundamental structure of the provision as intended by the legislature on this point and would even impose additional obligations on another state. In doing so, Swissmedic would go significantly beyond a mere concretization of the provision. 40

- 41 The *form* that foreign authorities must complete and submit to Swissmedic prior to an inspection is, however, worded much more cautiously. It merely states that the foreign authority is “requested” to send a copy of the inspection report to Swissmedic after it has been prepared. There is no mention in the form of a prior “acceptance” of such an obligation. All in all, therefore—notwithstanding the fact that the wording in the Swissmedic “information sheet” may suggest otherwise—that the requirement set forth in Art. 64a para. 1 lit. d is, from a legal technical standpoint, a (resolutive) condition (and not a “factual” prerequisite) for the legality of foreign inspections in Switzerland.
- 42 Finally, the requirements outlined above must be met **cumulatively**. This means that if even one of the requirements is not met, the foreign authority loses its authorization to conduct an inspection in Switzerland on the basis of Art. 64a para. 1. If the inspection is (or was) nevertheless carried out, it must be classified as unlawful under (international) law and is punishable under Art. 271 of the SCC. In this context, only the requirements under Art. 64a para. 1 lit. a and c constitute actual *prerequisites* for invoking the authority. If these are met, the inspection in question may be carried out without further ado. The requirements under Art. 64a para. 1(b) and (d), on the other hand, are *conditions of validity* for the lawfulness of the inspections. They become relevant only after an inspection has been carried out and, if not met, subsequently render the inspection in question unlawful (see above N. 30 ff., N. 39).

## 2. Specification by Swissmedic

- 43 The provision of Art. 64a(1) requires further specification in several respects. Such specifications were made (exclusively) by the Swiss Agency for Therapeutic Products, namely in the form of an “information sheet” and a “notification form,” through which cross-border inspections to be conducted on the basis of Art. 64a(1) must be reported. Swissmedic’s **authority** to carry out these clarifications can be based—albeit only with a great deal of goodwill—on Art. 60(1). It is true that, in addition to the Federal Council, Swissmedic is in principle also responsible for enforcing the TPA – which includes the elaboration of statutory provisions – (Art. 82 para. 1). However, under the system established in Art. 82, Swissmedic is only granted enforcement authority if the TPA designates the institute as competent or if the Federal Council has delegated to it the power to issue “provisions of a technical nature and of secondary importance.” The latter has not occurred in the present case. In this

context, it should be noted that Swissmedic – and presumably also SECO – apparently sought, within the framework of enshrining and partially modifying the former administrative practice in Art. 64a, to ensure that *the Institute* would now assume the central role in this area. However, the legislature evidently did not follow this approach – Art. 64a does not imply such a far-reaching function for Swissmedic.

In light of the foregoing, only provisions of the TPA Act—and specifically only Art. 60—can serve as the basis for Swissmedic’s authority to implement specific measures. In Art. 60(1), the Institute is generally declared—subject to certain reservations that are not relevant here—to be “responsible for inspections in Switzerland.” This is intended to cover “all conceivable inspections” and thus, among other things, also “inspections at the request of a foreign authority.” However, Art. 60 primarily concerns the *allocation of responsibility for conducting inspections between Swissmedic and the cantons*. Against this background, there are at least some doubts as to whether Swissmedic is (also) competent, on the basis of this provision, to use Art. 64a to specify a provision of the TPA that grants other states certain rights in relation to Switzerland and thus has implications under international law. In view of the latter circumstance, it might be more reasonable to assume that this falls under the jurisdiction *of the Federal Council*. Regardless, however, the current situation is evidently tolerated without objection by all involved parties (primarily the Federal Council, SECO, the FDFA, affected companies, and foreign authorities)—a phenomenon, incidentally, that can also be observed in other areas of the pharmaceutical sector.

The requirements set forth in Art. 64a(1) are specified in the Institute’s “Information Sheet” and “Notification Form” as follows:

The foreign authority must, among other things, provide **information** regarding the “purpose” of the notification (notification of a new inspection, change, or cancellation of an already notified inspection), the inspecting authority, and the planned inspection (company to be inspected, dates, participating authority representatives, etc.) as well as the type of inspection (GMP, medical devices, etc.; market surveillance inspection, inspection following an incident, etc.).

With regard to the **notification deadline**, Swissmedic has stipulated that a planned inspection must be notified *at least 30 days in advance*. This speci-

fies the requirement set forth in the preamble to Art. 64a(1) that cross-border inspections must be notified *in advance* (see N. 17 above). As already mentioned, it may appear doubtful whether Swissmedic itself is authorized to make such specifications. For essentially, this specification means that an inspection that is notified (for example) only 20 days in advance does not meet the requirements under Art. 64a para. 1 and, consequently – should it be carried out nonetheless – is unlawful under (international) law. Furthermore, the representatives of the foreign authorities involved are liable to prosecution under Art. 271 of the SCC. In view of these—not insignificant—circumstances, it must be assumed that the relevant clarification should rather have been made by the Federal Council itself (see N. 43 above).

- 48 Regarding the requirement set forth in **para. 64a(1)(c)** for the **consent of the facility to be inspected** (see N.s. 33 et seq. above), Swissmedic has specified that such consent must cover the dates, the representatives of the authorities, the nature, and the scope of the inspection.
- 49 With regard to the requirement set forth in **Art. 64a para. 1(d)**, according to which the foreign authority must inform the institution of the outcome of the inspection by **delivering the inspection report** (see above N. 39 et seq.), Swissmedic has specified that this must occur *within ten days of the “adoption” of the report*, although, as an alternative to the actual inspection report, *a one-page summary* may also be submitted; however, this must be done within 40 days of the inspection. As regards the ten-day deadline, the same concerns apply regarding Swissmedic’s authority to make such clarifications as those relevant to the reporting deadline. The alternative of to submit only a summary of the inspection report does not merely constitute a clarification, but actually represents a *relaxation* of the requirement set forth in para. 64a(1)(d)—and thus a *substantive amendment to the law*. Swissmedic is clearly not authorized to do so. As a result, all inspections following which foreign authorities submit only summaries of the relevant inspection reports essentially fail to meet the requirement set forth in Art. 64a para. 1 lit. d. However, this does not necessarily mean that the inspections in question subsequently become unlawful under (international) law. This is because, under certain circumstances, Switzerland must accept the regulation enacted by Swissmedic despite the lack of jurisdiction. Domestic rules on jurisdiction may be irrelevant under international law in this regard. This applies in particular when the lack of jurisdiction of the acting authority is not “blatantly obvious.” This is likely to

apply in the present case—the fact that Swissmedic, as the competent authority, was actually not competent to adopt the regulation in question here is unlikely to be immediately apparent to other states. As for the potential criminal liability of the foreign authority representatives involved in the inspections under Art. 271 no. 1 of the SCC, it should be noted that the act’s violation of international law is not a prerequisite for criminal liability under this provision. Consequently, criminal liability may in principle exist even if the act is lawful under international law; this is particularly true in circumstances such as those relevant here, where compliance with international law arises, so to speak, only “indirectly.” However, the very fact that the institute’s lack of jurisdiction is not “quite obvious” here is likely to be taken into account as a mitigating factor precluding criminal liability.

### C. Accompaniment by Swissmedic (para. 2)

Pursuant to Art. 64a para. 2, Swissmedic may “accompany” foreign authorities 50 when they conduct inspections in Switzerland on the basis of the authorization under para. 1 of the provision. Whether Swissmedic makes use of this option in individual cases is decided by the Institute on a case-by-case basis, taking into account the specific circumstances, after it has received the notification pursuant to Art. 64a para. 1. If it decides to provide such accompaniment, both the foreign inspectors and the facility being inspected in Switzerland must tolerate the presence of Swissmedic representatives. For the foreign inspectors, this stems from the fact that Switzerland is entitled to establish the framework conditions for the presence and activities of representatives of other states on its territory. With regard to the establishments to be inspected, the obligation to tolerate such presence arises directly from Art. 64a para. 2.

The **function** of Swissmedic’s accompaniment is primarily to have official 51 Swiss government representatives observe on-site whether the parameters reported for the foreign inspection and the requirements under Art. 64a para. 1 are being complied with—a task that would otherwise be left solely to the inspected facility.

The law is silent on the **powers** of Swissmedic representatives in the context 52 of such accompaniments. It can be assumed that these powers generally correlate with the aforementioned function of the accompaniments. As is evident in particular from the wording of the law—“accompaniment”—Swissmedic

representatives primarily have a purely *observational*, i.e., passive, role. In particular, Swissmedic generally has no authority to actively intervene with regard to foreign inspectors (i.e., to prohibit them from carrying out certain actions on site) . If it does so nonetheless—for example, because it believes that the inspection is unlawful in a specific respect—it quickly enters a legally problematic area under (international) law, since the foreign inspectors are generally official representatives of authorities (see above N. 5, N. 16).

- 53 Swissmedic’s participation in a foreign inspection does not, in principle, constitute **an inspection of the institution**. Accordingly, Swissmedic may not, on its own initiative, impose measures against the inspected facility based directly on findings made during such participation, unless there is a specific legal basis for doing so. Art. 64a para. 2 alone does not constitute such a basis. Notwithstanding this, however, Swissmedic is authorized to use findings and observations it obtains during accompaniments within the meaning of this provision as grounds for initiating separate investigations, inspections, etc., with respect to the establishment concerned. *These* may ultimately result in administrative measures against the facility. A different rule applies only in individual cases where there is a **joint inspection** by Swissmedic and a foreign authority (“Joint Inspection”). However, such an inspection must also be announced to the facility concerned in advance, and it must also comply with all other relevant procedural requirements.
- 54 Swissmedic’s participation in a foreign inspection has no **legal effect** whatsoever with regard to the (international) legality or criminal liability of the inspection under Art. 271 of the SCC. In particular, such participation in no way “cures” any non-compliance by the foreign authority with the requirements arising from Art. 64a para. 1, and Swissmedic has no authority whatsoever to approve such non-compliance “spontaneously on the spot” as an exception or the like. However, such “approvals”—should they occur in individual cases—are not entirely without legal significance. For Switzerland must, under certain circumstances, accept Swissmedic’s actions as binding from the perspective of international law, despite the lack of jurisdiction. And as regards the potential criminal liability of the foreign authority representatives involved in the inspections under Art. 271 no. 1 of the SCC, an action by Swissmedic in the sense outlined here could ultimately be taken into account at the level of culpability .

Art. 64a(para. 2) refers exclusively to accompaniment by “the Institute.” In 55  
 practice, however, it also occurs that foreign inspections are (solely) **accompanied by representatives of the cantons**. This possibility is expressly provided for in a document from the “Swiss Medicines Inspectorate.” This approach is consistent with Art. 64a para. 2 to the extent that Swissmedic has delegated inspections pursuant to Art. 60 para. 3 to the cantonal inspectorates. Furthermore, accompaniment by cantonal inspectors may also be based on Art. 60 para. 4.

#### D. Swissmedic Inspections Abroad (para. 3)

Finally, pursuant to Art. 64a para. 3, Swissmedic “may” conduct inspections 56  
 abroad of establishments operating in the medicinal products sector. However, this is only permitted after consultation with the competent foreign authorities and to the extent that it is “necessary to ensure the protection of public health.” According to the “clarification” added in 2019, Swissmedic may also participate in inspections conducted by competent foreign authorities.

Para. 3 of Art. 64a is a **purely jurisdictional provision**. That is to say, it 57  
 merely establishes—and exclusively under Swiss law—Swissmedic’s authority to to conduct inspections abroad. By contrast, the provision has no bearing whatsoever on the admissibility of such inspections under international law or under the law of the state concerned and, consequently, also on any potential criminal liability under Art. 299 of the SCC (unauthorized performance of official acts on the territory of other states; see above N. 9 ff.) . In particular, Art. 64a para. 3 *does not* mean that inspections abroad are automatically to be classified as “unauthorized” within the meaning of Art. 299 no. 1 SCC.

Swissmedic’s authority to conduct inspections abroad on the basis of Art. 64a 58  
 para. 3 is, however, subject to several **conditions**. First, inspections may be conducted exclusively on *establishments operating in the field of medicinal products*. Whether a particular establishment “operates in the field of medicinal products” is assessed according to *Swiss* law, i.e., based on whether the enterprise in question is active in the field of medicinal products or medical devices within the meaning of the TPA. In this regard, the comments made above in N. 19 ff. apply, so to speak, “with the opposite sign.”

Furthermore, inspections may only be conducted *after consultation with the* 59  
*competent foreign authorities*. The stipulation of this requirement in Art. 64a

para. 3 is essentially superfluous, since conducting inspections abroad without the knowledge of the affected state—or without “consultation” with its competent authorities—is contrary to international law and must be refrained from for this reason alone. Furthermore, the “competent authorities” are not limited to the corresponding specialized agencies of Swissmedic (e.g., the FDA in the case of the United States), but—depending on the applicable legal framework—also those authorities that must grant the consent required under international law to conduct the inspections on their territory (see above N. 6).

- 60 Finally, for a specific inspection to be carried out by Swissmedic abroad on the basis of Art. 64a para. 3, it must be *necessary for ensuring the protection of health*. It goes without saying, first of all, that “protection of health” refers to that *in Switzerland*. This term must then—in the sense of a systematic interpretation – in light of the purpose of Art. 1 para. 1, which (very similarly) refers to the “protection of health” (of humans and animals), which in turn is to be ensured by the fact that “only high-quality, safe, and effective medicinal products” are placed on the market in Switzerland. This triad already serves, in the context of Art. 1(1), as a benchmark for determining what is (still) covered by the purpose of “health protection.” It can also be invoked within the framework of Art. 64a(3) to clarify the limits of the Institute’s authority as set forth therein. Accordingly, Swissmedic is in principle authorized to conduct inspections abroad (only) if this serves to ensure that only high-quality, safe, and effective medicinal products are placed on the market in Switzerland.
- 61 However, a specific inspection must not merely serve these purposes; rather, according to the wording of the law, it must *benecessary* to ensure the protection of public health. Accordingly, an inspection abroad must not be carried out (or Swissmedic is not authorized to carry it out at all) if it can be ensured by other means that only high-quality, safe, and effective medicinal products are placed on the market in Switzerland. This significantly restricts the Institute’s authority as set forth in Art. 64a para. 3.
- 62 This, in turn, raises the question of what the **consequences** are **if Swissmedic does not adhere to the limits of its authority under Art. 64a para. 3** (e.g., inspects a business abroad that operates in the food sector rather than the medicinal products sector). Such inspections are fundamentally unlawful; however, this generally does not render them void but merely subject to challenge. The unlawfulness must primarily be asserted in Switzerland,

which typically poses greater hurdles for foreign businesses that have been or are to be inspected. Inspections exceeding the Institute's jurisdiction may also, under certain circumstances, give rise to claims for state liability.

According to the second sentence of Art. 64a(3)—which was added subsequently and entered into force in May 2021—the Institute may then “**participate in inspections conducted by competent foreign authorities.**” This is intended specifically in the context of “joint assessments” in procedures for the designation of conformity assessment bodies. This “clarification” is actually merely a clarification, since the institute's authority to conduct inspections abroad independently, *a maiore ad minus*, also covers the authority to merely participate in inspections by foreign authorities. Therefore, the clarification or “clarification” is essentially superfluous. With regard to the framework conditions for such participation, the remarks made above in N. 57 ff. apply *mutatis mutandis*. 63

**Further framework conditions** for the exercise of the authority established in Art. 64a para. 3 abroad are then governed by foreign law and—where applicable and relevant—by treaties or international agreements (both for independent inspections and for those in which Swissmedic merely participates—within the meaning of Art. 64a para. 3, sentence 2). However, this does not concern the (limits of) the authority under Art. 64a para. 3, but rather the modalities of its concrete *exercise* abroad. For just as Switzerland has regulated the framework conditions for inspections within its territory by authorities of other states (Art. 64a para. 1 and 2; see above N. 14 ff.), states in which Swissmedic intends to conduct inspections in the exercise of its authority under Art. 64a para. 3 may likewise establish framework conditions for such inspections. 64

Finally, Art. 64a para. 3 also refers only to the “Institute” as the competent authority. In practice, however, it sometimes happens that **representatives of the cantons also participate** in inspections abroad. This possibility is expressly provided for in a document issued by the “Swiss Medicines Inspectorate.” Insofar as the leadership of the inspection team lies with Swissmedic—as stipulated in the Swiss Medicines Inspectorate's guidelines—this approach is to be regarded as compatible with this provision, notwithstanding the fact that it does not follow directly from the wording of Art. 64a para. 3. 65

### III. RELATIONSHIP TO AGREEMENTS ON THE MUTUAL RECOGNITION OF INSPECTIONS

- 66 In the recent past, Switzerland has concluded a number of agreements with other countries in which, among other things, it was agreed to mutually recognize the results of domestic inspections in specific sectors of the medicinal products field. The most recent example is the agreement concluded in January 2023 with the United States of America in the area of Good Manufacturing Practice (GMP) for medicinal products. Under this agreement, the two countries mutually recognize, in principle, the inspections conducted by their respective national authorities responsible for carrying out GMP inspections in their respective countries (Swissmedic and the FDA). This is ultimately intended to avoid duplicate inspections at the same site or by the FDA and Swissmedic.
- 67 Regarding the relationship between Art. 64a and agreements such as the one mentioned above, it should first be noted that this provision cannot in any way serve as a legal basis for the conclusion of such agreements. Accordingly, the conclusion of such agreements must be based either on Art. 82a or on the general provisions governing the conclusion of international treaties. Furthermore, “cross-border” inspections within the meaning of Art. 64a will lose significance to the extent that the number of agreements such as the one mentioned above, concluded between Switzerland and the United States, increases. For, as already explained, one of the objectives of such agreements is precisely that the results of inspections conducted by domestic authorities be recognized or adopted by foreign authorities for their own purposes. This renders independent inspections by the relevant foreign authorities obsolete.

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