



New Medical Device Regulation (MDR) Catch 22: How should the Person Responsible for Regulatory Compliance (PRRC) balance the competing reporting and confidentiality obligations?

The PRRC fulfills an important function in the reporting system (vigilance), ensuring that the manufacturer or the authorized representative fulfills its legal obligations. The reporting, however, is in conflict with the contractual loyalty and confidentiality obligations, and its violation may call for sanctions under labor or criminal law. In the following, we show you how to solve the Catch 22 dilemma inherent to the PRRC's position.

The manufacturer's reporting obligations attend to any serious incidents that can be attributed to the medical device or its use and that could endanger or impair the health of third parties. Exempt are side effects that are clearly documented in the product information, quantified in the technical documentation, and set out further in the trend reports. The reporting obligations also include quality defects and any further findings and assessments that might influence the basis for the product's evaluation. In Switzerland, however, the reporting obligations for medical devices are limited to events that have occurred in Switzerland. Exempt from the reporting obligations are events that have occurred abroad. The notification to the Swiss authorities shall be made in line with the rules of Good Vigilance Practice.

The *time limit* for fulfilling the reporting obligations depends on the severity of the incident:

- ❖ If there is a serious threat to public health, the notification must be provided

2 days after the manufacturer's becoming aware of the threat.

- ❖ In all other cases the notification must be made 15 days after the manufacturer becomes aware of the incident or has established the causal relationship between the incident and the product.

To fulfill the reporting obligation in due time, the law provides the manufacturer with the opportunity to file a preliminary report and to follow up with a complete report at a later date. This also applies if there is uncertainty as to whether the incident must be reported at all.

In the case of foreign manufacturers, the Swiss authorized representative must ensure that the reporting obligation is fulfilled. The report may be made by either the manufacturer or by the authorized representative. Both the procedure and the responsibilities for fulfilling the reporting obligation must be set out in the mandate agreement between the manufacturer and the authorized representative.

Duties of the PRRC

The PRRC is responsible for fulfilling the manufacturer's reporting obligations. A violation of the reporting obligation may be sanctioned by criminal law. Punishable is even the negligent omission of a notification. Therefore, for criminal sanctions, it is sufficient for the PRRC to fail to make a report, even though she/he could have recognized, on the basis of her/his experience, that a reportable situation occurred.

The reporting is not limited to serious incidents. Rather, the PRRC is entitled to report "observations" that might suggest that a violation of the regulatory requirements have occurred. For that purpose, the PRRC may contact the Swiss authorities directly - without contacting the employer first. Swiss authorities treat such voluntary notifications confidentially and protect the identity of the person making such notification from disclosure to her/his employer.

Confidentiality obligations

The PRRC is obliged to be loyal to the manufacturer or the authorized representative. The loyalty obligations apply regardless of whether the PRRC is acting as an employee or as a contractor. Both employment and agency law requires that the PRRC safeguard the interests of the principal and refrain from doing anything that could be economically detrimental to her/him. The loyalty obligations also include the obligation to keep confidential all information that is neither obvious nor generally accessible, but in which the principal has a legitimate interest to maintain secrecy.

Whether criminal acts and violations of administrative regulations are also subject to the duty of confidentiality is a matter of legal dispute. At the time of a contested disclosure, however, unlikely is there certainty as to whether the information concerns an unlawful or even criminal activity. Therefore, the reporting of allegedly unlawful conduct always bears the risk that the reported action might be

deemed lawful in a complex future investigation – where the PRRC will at the end be accused to have violated her/his loyalty and confidentiality obligations. Any such accusation is all the thornier because the unauthorized disclosure of business and trade secrets can also be punished under criminal law.

Right or obligation to report?

The regulatory reporting obligations, the contractual loyalty obligations, and the protection of business and trade secrets tread a fine line in terms of their objectives. If the PRRC fails to make the legally required report, she/he is liable to criminal prosecution. The PRRC, however, is also liable to prosecution in the opposite case: if she/he reports a matter that is not subject to the mandatory reporting obligations. To the extent that a reporting is not required in the legal sense, the PRRC violates the company's business and manufacturing secrets.

Against this background, the correct fulfillment of the reporting obligation represents a great challenge to the PRRC: Due to pressing time, the limited information available, and the need for factual interpretation, it is rarely possible to adjudicate with sufficient certainty whether a reporting obligation exists at all. However, if the PRRC waits too long, she/he also violates the reporting obligations as well, and is again liable for prosecution.

No protection against disadvantages

Swiss law provides that the PRRC should not suffer any disadvantages when fulfilling the necessary duties correctly. However, this legal privilege applies only if the report or its omission was objectively justified. Adding to this caveat: whether the reporting obligations existed at all can only be assessed in retrospect. The provision is therefore not suitable for removing the uncertainty when the PRRC needs to make the decision whether or not to report. This is the Catch 22. The challenge for the PRRC is

even more tricky, because Swiss law does neither provide for a reversal of an unjustified dismissal nor can reinstatement be enforced by court action - even if the report should prove to be justified. In view of the reparation owed of a maximum of 6 months' wages, the PRRC is not sufficiently protected from disadvantages, even if she/he acts correctly. Against this troublesome background, it is all the more important to exempt the PRRC from sanctions if it later turns out that the report was not legally required.

What is to be done?

There is a tradeoff between the statutory reporting obligations and the contractual confidentiality obligations. To resolve this conflict of

objectives, the company and the PRRC must clarify and mutually agree upon the procedure and lay it down in detailed work instructions. To provide the PRRC with additional security, the parties may agree to restrict the PRRC's liability to intent or gross negligence. The personal liability of the PRRC may also be limited in monetary terms, for example, to a certain maximum financial amount or to a percentage of the PRRC's annual salary. These contractual measures strengthen the position of the PRRC and improve her/his independence in performing the contractual and legal duties. Ultimately of course, this is in the company's own interest.

Streichenberg advises companies with regard to the measures to be taken due to the new regulation of medical devices in Switzerland and in relation to the European Union. You can find further publications on our website at www.streichenberg.ch. Please contact us if you are interested in further information.

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