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PharmaCircular

New Medical Device Regulation (MDR)

Tasks and Duties of the Person Responsible for Regulatory Compliance (PRRC)

Since 26 May 26 2021, all manufacturers of medical devices and their authorized representatives must appoint a Person Responsible for Regulatory Compliance (PRRC). The PRRC is one of the main additions to the new medical device regulation. In the following, we lay out the tasks of the PRRC in Switzerland focusing on manufacturers of medical devices and in vitro diagnostics.

The PRRC assumes a critical function in the monitoring and control of medical devices, in particular with respect to the manufacturing, post-market surveillance, and vigilance. The PRRC is an equivalent to the responsible person in the pharmaceutical industry. By harmonizing its legislation with the EU MDR, Switzerland incorporates the PRRC into its own law but refers to European law for further details.

Who is affected?

To ensure regulatory compliance, manufacturers of medical devices and in vitro diagnostics must retain a PRRC in their organization. Appointing a PRRC does not relieve the manufacturer from its overall responsibility for its products and their compliance, but it ensures that the manufacturer has the necessary knowledge to implement the regulatory requirements in its organization.

Small and micro-enterprises may delegate the tasks of the PRRC to an external service provider. For this purpose, they must enter into a written agreement and must define its tasks and duties. Small and micro-enterprises are companies with fewer than 50 employees and annual sales of less than 10 million euros or an approximate amount in Swiss francs.

Tasks of the PRRC

The PRRC must fulfill specific obligations in the handling of medical devices and in vitro diagnostics. According to the EU MDR or EU IVDR, she/he is responsible for the following tasks:

- Checking the products according to the quality management system before they are released by the manufacturer;
- Preparing and updating the technical documentation and the declaration of conformity;
- Performing post-market surveillance; and
- Fulfilling the reporting obligations on serious incidents.

These tasks are sub-aspects of the quality management system. An efficient and effective quality-management system is essential for an efficient and effective monitoring of medical

devices. Only then can the PRRC fulfill its legal tasks. Consequently, the PRRC is in charge for the establishment, operation, and further development of the quality management system, including the system for risk management and post-market surveillance.

The PRRC need not fulfill the legal obligations alone. It is sufficient that these tasks are carried out under her/his responsibility. If the PRRC delegates some of the tasks to another person, she/he shall be responsible for selecting, instructing, and supervising that person. The details of implementation are to be specified in internal work instructions.

Substitution and part-time

Manufacturers must employ at least one person in their organization who carries out the tasks of the PRRC. Swiss law does not specify the degree of the employment. The scope of employment must be appropriate to enable the PRRC to fulfill all the legal duties. The adequacy of the employment is assessed on the basis of the circumstances and in consideration of each individual case. Full-time employment is neither always required nor always sufficient. Swiss law permits that one or more persons may carry out jointly the activities of the PRRC. The processes and responsibilities must be laid down in internal work instructions. In addition, any substitutions must be stipulated in writing.

Professional and personal requirements

The required qualifications for the PRRC defer depending on education and professional experience: The candidate must have at least four years of professional experience in regulatory affairs or quality management relating to medical devices, unless she/he obtained a university degree or an equivalent level of education, in which case one year of professional experience is sufficient.

With respect to the responsible person in the pharmaceutical industry, Swiss law requires that additional personal requirements are met, in particular, trustworthiness. According to the established practice of the Swiss enforcement authorities, trustworthiness is lacking if there is a final and enforceable conviction for an offense relevant to therapeutic products law. The responsible person in the pharmaceutical industry must also be able to speak at least one Swiss official language. It can be assumed that these requirements also apply to the medical device industry by way of analogy. Residence in Switzerland is not mandatory.

Independence

In accordance with the EU MDR and EU IVDR, Swiss law provides that the PRRC should suffer no disadvantage if all duties of the position have been complied with properly. According to the legislative materials, this provision ensures independence: In performing her/his duties, the judgement of the PRRC shall not be influenced by private interests.

The provision does not guarantee the PRRC's independence. Unlike the responsible person in the pharmaceutical industry, the PRRC has no authority to give binding instructions. In addition, Swiss law does not prohibit the PRRC from being a member of the management. Only in the case of a foreign manufacturer and the Swiss authorized representative, will the same person not be allowed to perform the tasks of the PRRC. For the same compliance considerations, the PRRC of a micro or small enterprise and the PRRC of the authorized representative shall not belong to the same external organization.

Likewise, the PRRC is not safe from any disadvantages, regardless of whether she/he fulfills all duties correctly. If a termination occurs due to disagreements, the PRRC cannot force reinstatement - even in court. This is the case even if no breach of duty can be proven. This lack of protection in Swiss labor law leaves the PRRC vulnerable to unjustified sanctions, thereby weakening further the PRRC's independence in

performing her/his duties. For their own protection, it is therefore important that the responsibilities and processes of their activities be clearly defined in internal regulations.

Implementation deadline

As of 26 May 2021, manufacturers must have appointed a PRRC. There are no transition periods for the implementation of this obligation. Market participants, however, must not register before 26 November 2021, or 3 months from the first time a product is made available in Switzerland. These deadlines also apply to the notification of the company and its PRRC to Swissmedic. Accordingly, there is some leeway in terms of time - at least until the Swiss authorities is given the name of the PRRC. However, once the name of the PRRC has been reported, Swissmedic must be notified within 7 days of any subsequent changes.

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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