Serious Incident Reporting for Medical Devices — Serious Implications of Nonreporting

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The Swiss Act on Therapeutic Products (TPA), Article 59, stipulates an obligation to notify Swissmedic about quality defects of and other findings on therapeutic products that may endanger the health of patients or influence the basis of evaluation of these products. This legal obligation applies not only to manufacturers but equally to healthcare professionals, hospitals, and others who prescribe and administer therapeutic products. This vigilance system is aimed at preventing the occurrence or recurrence of adverse events and reactions and thus at improving product and patient safety.

The best way to detect such problems at an early stage is to have them reported by the persons using the product (usually medical, medico-technical, and paramedical staff) or by the healthcare institutions that employ such persons.

Vigilance obligations with regard to medicinal products (pharmacovigilance) are well known, not only on the level of marketing authorization holders and distributors but also by doctors, pharmacists, and hospitals.

The same is less true for the so-called "materiovigilance," vigilance regarding medical devices (including in vitro diagnostics), notably on the side of the users of such products. It seems that in the course of Swissmedic's inspection activities, it came to light that hospitals were not sufficiently aware of the legal obligations to report serious incidents involving medical devices, nor of the necessity of having established vigilance reporting systems and processes (quality management). Medical, medico-technical, and paramedical staff often are not adequately (or even not at all) trained in materiovigilance, although these obligations are not only laid down as a general rule in Article 59 TPA but detailed in the Ordinance on Medical Devices (MedDO) and the Ordinance on in vitro diagnostic medical devices (IvDO). Any professional who discovers a serious incident during the use of such products is legally obligated to report it to the supplier and to Swissmedic, in accordance with Article 66, paragraph 4 MedDO, and Article 59, paragraph 4 IvDO.

Persons using medical devices and in vitro diagnostics as well as their superiors in hospitals are well advised to heed the vigilance reporting obligations, as violations may not only lead to administrative measures but are considered criminal offences under the TPA. Criminal prosecution may lead to fines up to CHF50,000 and, for professionals, even to monetary penalties (Art. 87, para. 1, letter c, and para. 2 TPA). Further, hospitals that fail to meet the necessary organizational requirements for reliable reporting by employed professionals using medical devices and in vitro diagnostics risk a fine up to CHF5 million if it is not possible to

attribute this omission to any specific natural person due to the inadequacy of the organization.

Don’t hesitate to contact our Swiss Life Sciences team through the authors of this article if you should need support in taking the required organizational measures or if you need to train your employees in materio- or pharmacovigilance.