Medical devices
Swissmedic inspects Class I manufacturers in Switzerland

Since 26 May 2021, manufacturers of Class I medical devices (for example surgical shavers, positioning aids, surgical masks or non-sterile wound dressings) have been obliged to ensure that their devices comply with the new regulation. Manufacturers confirm compliance with the new requirements in their **declaration of conformity**. Swissmedic must be notified of these devices.

The new regulation stipulates that devices must be subject to market surveillance (e.g. incidents involving the devices as well as trends that might indicate an increase in the number of complaints or the severity of incidents). Continuous and systematic post-market surveillance is the only way that manufacturers can verify that medical devices offer patients the promised benefits and that no unexpected risks occur, including device failures or safety issues.

The procedure for post-market surveillance by manufacturers is prescribed by law. Manufacturers are obliged to draw up a **post-market surveillance (PMS) plan** for each device they place on the market. At intervals defined by the manufacturer, the collected post-market data are evaluated in a **PMS report** and measures are defined on the basis of this evaluation.

In most cases, manufacturers have to submit their medical devices to an independent testing body (notified/designated body) for an assessment procedure before they can market them. Class I medical devices are exempt from this requirement by virtue of the low risks associated with them. Swissmedic therefore launched a focus campaign to investigate how the new regulation was being implemented with regard to these otherwise unmonitored devices. Between August and December 2022, Swissmedic reviewed declarations of conformity, evidence that Swissmedic had been notified of the devices, and post-market surveillance plans and reports in a random sample of 27 manufacturers (approximately 8% of all Swiss manufacturers identified at the time the data analysis was conducted).

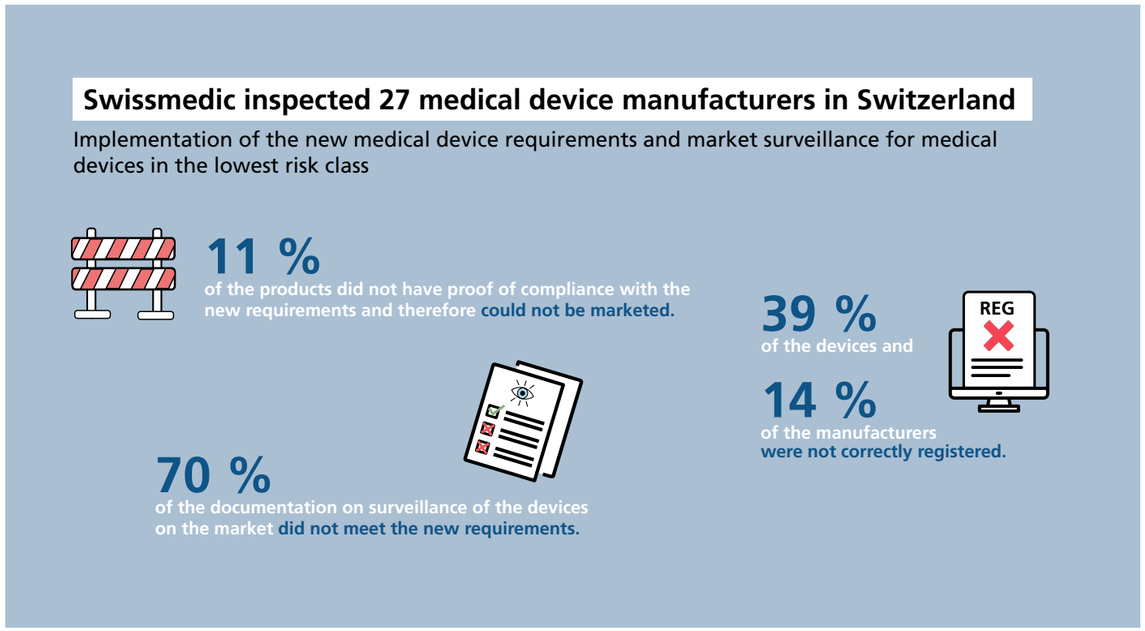
As work progressed, it became apparent that 14% of the manufacturers in the sample were not registered with Swissmedic when the review took place. Initially, it was found that Swissmedic had not been correctly notified of 39% of the Class I medical devices reviewed. The outstanding and incorrect manufacturer and device registrations / notifications were dealt with during the review.

11% of the manufacturers whose declarations of conformity were reviewed were unable to demonstrate fulfilment of the new legal requirements (no declaration of conformity in accordance with MedDO/EU MDR). Without this proof, however, devices may not be placed on the Swiss market. Swissmedic notified the manufacturers of corresponding measures, as a result of which the majority of manufacturers subsequently submitted confirmation of compliance with the new requirements. Manufacturers who did not provide confirmation were prohibited from placing the devices in question on the market.

Overall, 70% of the post-market surveillance documentation reviewed failed to meet legal requirements. As a result, manufacturers were unable to demonstrate continuous and systematic surveillance of their devices on the market. The majority of these deviations from legal requirements (non-conformities) concerned data collection and the evaluation of (serious) incidents and trends. As part of the review procedure, manufacturers were given the opportunity to rectify the deficiencies identified within a specified deadline. Swissmedic will continue to review manufacturers' updated documentation and monitor the corrective actions. If the deviations are not rectified, Swissmedic will impose additional measures.

The review demonstrates that manufacturers of Class I medical devices are not adequately implementing the Medical Devices Ordinance, despite it having been in force for 18 months. This applies particularly to post-market surveillance. The focus campaign succeeded in obtaining corrective actions from the affected manufacturers and in making the market as a whole aware of the implementation of the new requirements.

Swissmedic has no indication that the situation at foreign manufacturers could be fundamentally different and will continue to monitor it if necessary. The **Swiss Da**tabase on **Me**dical **D**evices – swissdamed – which is currently being developed, will increase transparency as regards the devices on the Swiss market and give Swissmedic a data resource for more comprehensive, wider-ranging controls.



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