Medical devices in the media spotlight

‘Implant Files’ is a Europe-wide media phenomenon featuring critical reports on medical devices. Swiss Medtech believes that it is important to have an open and objective discussion on the opportunities and risks of medico-technical progress and involves all actors in the healthcare sector in this discussion. Sensational articles that put patients on edge are not helpful.

Patient safety is top priority
Patient safety is top priority for the Swiss medical technology industry. Around 500,000 different medical devices are used in healthcare to save lives, relieve suffering, analyse diseases and improve the quality of life of millions of people around the world. Medico-technical progress is rapid and calls for safety requirements to be reviewed and adapted constantly. However, no matter how strict the regulation, risks cannot be eliminated entirely, nor can criminal behaviour be prevented entirely.

Safety improved even more
The new EU Medical Device Regulation (MDR) came into force at the end of May 2017. It must be adopted from 2020 at the latest after a period of transition. The already stringent requirements for testing laboratories, product manufacture, clinical data and market surveillance will be further increased. The overarching goal of the stricter regulations is to increase patient safety. Swiss Medtech stands unreservedly behind this goal. The Swiss medical technology industry is working very hard to implement the new regulations.

Transparency benefits us all
Swiss Medtech welcomes the increase in transparency brought by the MDR. Thanks to a unique product identification number (UDI) and its display in the central, publicly accessible EU database EUDAMED, medical devices will be identifiable and traceable. The database will also contain information on the manufacturer, reports on the safety and clinical rating of the product, and notifications of product defects. Increased transparency benefits us all – patients, medical institutions, doctors and carers as well as health insurance providers, patient organisations and manufacturers.

Open and objective discussion
Swiss Medtech sees the new MDR regulatory system as another step in the right direction towards improving the safety and quality of medical devices. However, from the association’s point of view, it is essential that the level of quality of certification and surveillance is fully maintained throughout the period of transition from the old system (MDD) to the new system (MDR). In order to achieve this, there must be a sufficient number of officially recognised testing laboratories that can also deal with the additional tasks from the moment the new system comes into force. Swiss Medtech has thus identified a risk which could affect security of supply and even product safety across Europe. Consequently, the association is pushing for this risk to be given the attention it deserves across Europe.

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