

Non-invasive ventilation

Product failures in anesthetic apparatuses and their consumables - Analysis of field safety notes published by the BfArM 2005-2013

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The current European system regulates marketing and post market surveillance of medical devices in the European Economic Area. In cases of incidents and Field Safety Corrective Actions (FSCA) manufacturers have to inform responsible Competent Authority (D: BfArM) and public by Field Safety Notices (FSN). We analysed FSCA and FSN for anesthetic apparatuses and consumables published by BfArM 2005-2013 in respect to MEDDEV 2.12-1 rev 8. Of 29 FSCA published German and English FSN were found in 28/26 cases (24/22 apparatuses), respectively. FSN were clearly characterized as FSN in 25/20 cases and declaration of the type of action was found in 23/24 cases. Product names were provided in 28/26 cases. Lot numbers or other information for product characterization were available in 3/2 and 21/19 cases. Detailed information regarding FSCA were found in 28/25 cases and a declaration of the reportable incidence were found in 28/26 cases, respectively. Information on product related risks with previous use of affected devices was provided in 26/23 cases. In all cases manufacturers provided information to mitigate product related risks. Requests to pass FSN to persons needing awareness in the organization were found in 22/20 cases. Contact data were provided in 25/21 cases. Typical risks of reportable incidents in apparatuses were manufacturing errors (e.g. failure of electrical components) and software issues resulting in anesthetic risk (delay or stop of therapy) or user risk (e.g. tilting danger) and production failure in consumables resulting in anesthetic risk. Typical FSCA were additional recommendations for use or device reconstruction by the manufacturer. The vast majority of FSN fulfil the most important MEDDEV criteria, e.g. indication of the reportable incidence, or declaration of correct instructions for risk minimization. However, some criteria as risk classification as well as type and content of FSN should be further improved as FSA play an important role in cases of product failure of products already in the market.