PRODUCT FAILURES IN RESPIRATORS AND 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 respirators and consumables published by BfArM 2005-2013 in respect to MEDDEV 2.12-1 rev 8. Of 60 FSCA published German and English FSN were found in 59/53 cases, respectively. FSN were clearly characterised as FSN in 44/38 cases and declaration of the type of action in 45/44 cases. Product names were provided in all cases. Lot numbers or other information for product characterization were available in 7/7 and 43/40 cases. Detailed information regarding FSCA and product malfunction were found in all cases. Information on product related risks with previous use of affected devices was provided in 42/38 cases. In 53/53 cases manufacturers provided information to mitigate product related risks. Requests to pass FSN to persons needing awareness were found in 27/24 cases. Typical causes of product failure were software errors and faults in raw material, construction or manufacturing of the product followed by loss of function, missing alarms, short circuit and burn and impaired gas transport causing risk to patients and users. Most frequent FSCA were recall and customer information. FSN mostly fulfil the MEDDEV criteria. However, due to the importance of FSN for reduction of product related risks in FSCA type and content of FSN should be further improved.