PRODUCT PROBLEMS OF IMPLANTABLE PUMPS FOR DRUG THERAPY – ANALYSIS BASED ON FIELD SAFETY NOTES PUBLISHED BY THE BFARM 2005-2016

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The 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 issues for implantable pumps and consumables based on FSCA published by BfArM 2005-2016. Totally, after exclusion of follow-up reports 37 FSCA/FSN were available, affecting pumps/control devices (27) and catheters (10). Devices mostly served for intrathecal treatment of pain (e. g. morphine in cancer) and spasticism whereas other indications were rare. Pumps were at risk for material failure, software failure and handling problems resulting in risk of over- and underdosage with corresponding clinical symptoms; however, reported deaths were rare. Catheters were typically affected by material or production failures and at risk for occlusion (risk for underdosage), infection or bleeding. For risk reduction in pumps manufacturers performed customer information for prevention of product failure, intermittent distribution stop and device modification. However, catheters were typically subject of recall and customer information. In summary implantable pumps and devices are an important group of medical devices and published FSCA provide valuable information on existing product problems.