DO CUSTOMER INFORMATIONS IN CASES OF PRODUCT PROBLEMS OF TESTS AND REAGENTS FOR INFECTION TESTING FULFIL MEDDEV CRITERIA - ANALYSIS OF DATA PUBLISHED BY THE BFARM 2005-2012

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The European Directive 98/79/EC on In-vitro Diagnostics (IVD) regulates marketing and post market surveillance of IVD in the European Economic Area. In cases of incidents and field safety corrective actions (FSCA) manufacturers have to inform the responsible Competent Authority (CA; D: BfArM for most IVD) and the public by field safety notices (FSN). We analysed FSCA and FSN of tests and reagents for infection testing published by the BfArM 2005-2012 in respect to the MEDDEV 2.12-1 rev 8. 150 FSCA regarding these products were published. German and English FSN were found in 142 and 138 cases, respectively. FSN were clearly characterized as FSN in 121/128 cases and product names were provided in 139/114 cases. Lot numbers were provided in 113/113 cases and other information for product characterization was available in 99/111 cases. Detailed information regarding FSCA and product malfunction was found in 142/137 and 130/124 cases. Information on product related risks with previous use of affected IVD was provided in 97/99 cases. In 138/136 cases manufacturers provided information for mitigation of product related risks including retesting in 62/70 cases. Requests to pass FSN to persons needing awareness were found in 91/72 cases. Contact data were provided in 109/117 cases. Confirmation that a CA was informed was found in 32/34 cases and in 116/100 cases a customer confirmation form was included. Our data demonstrate that most FSN fulfil the MEDDEV criteria. However, due to the importance of FSN for mitigation of product related risks FSN should be further improved.