FIELD SAFETY NOTICES RELEASED BY MANUFACTURERS IN CASES OF FAILURE OF PRODUCTS FOR INFECTION DIAGNOSTICS: ANALYSIS OF CASES REPORTED TO THE BFARM BETWEEN 2005 AND 2007

R. Siekmeier, K. Lisson, and D. Wetzel

Federal Institute for Drugs and Medical devices (BfArM), Bonn, Germany

The European Directive 98/79/EC for in-vitro diagnostic medical devices (IVD) regulates marketing and post marketing surveillance of IVD in the European Economic Area. Manufacturers have to inform the responsible Competent Authorities (CA) about incidents and field safety corrective actions (FSCA) related to IVD. In Germany, the Federal Institute for Drugs and Medical Devices (BfArM) is the responsible CA for most IVD (only few IVD (no analysers), specified in Annex II of the Directive are under the responsibility of the Paul-Ehrlich-Institute (PEI)). In case of FSCA manufacturers have to inform customers by means of Field Safety Notices (FSN) which shall be sent to the BfArM prior to release and are also published on the BfArM homepage. Between begin of 2005 and end of 2007 the BfArM received a total of 1025 reports regarding IVD. From these 38 related to tests and reagents for infection diagnostics, 13 to analysers (8) and general consumables (5) based on culture techniques and 7 to analysers (5) and general consumables (2) based on molecular biological means. Analysers and general consumables based on immunological methods were excluded from our study because these are often multifunctional analysers which serve for the analytics of a large spectrum of non-infectiological parameters in clinical chemistry. FSCA were performed in Germany in 32 (84.2%) of cases related to tests and reagents, as well as 13 (100%) and 7 (100%) of cases related to analysers and consumables based on culture techniques and molecular biological means, respectively. For tests and reagents written FSN were received in German and English language in 31/27 cases delayed up to 56/42 days after notification to the BfArM, respectively. Product failures were sufficiently described in the text in 29/25 cases and the required measures were sufficiently described in 29/25 cases, respectively. However, there were cases with differences in the information quality between the German and the English versions. A customer confirmation form was part of the customer information in 24/17 cases only. In cases of failures related to analysers and consumables based on culture techniques written FSN were received in German and English language in 13/13 cases delayed up to 0/98 days after notification to the BfArM, respectively. Product failures were sufficiently described in the text in 13/13 cases and the required measures were sufficiently described in 13/13 cases, respectively. A customer confirmation form was part of the customer information in 11/9 cases only. In cases of failures related to analysers and consumables based on molecular biological means written FSN were received in German and English language in 7/6 cases delayed up to 72/47 days after notification to the BfArM, respectively. Product failures were sufficiently described in the text in 6/5 cases and the required measures were sufficiently described in 6/5 cases, respectively. A customer confirmation form was part of the customer information in 5 / 2 cases only. Our results suggest that for IVD for infection diagnostics FSCA and FSN are frequently performed. A number of relevant deficiencies regarding the quality of the FSN are demonstrated. In detail,

manufacturers should shorten the time until release and improve the contents of FSN to ensure the safety of IVD in cases of product failure.