ANALYSIS OF NOTIFICATIONS RELATED TO POINT OF CARE SYSTEMS FOR MEASUREMENT OF BLOOD GASES AND ELECTROLYTES RECEIVED BY THE BFARM UNTIL END 2011

R. Siekmeier, W. Lauer

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

The European Directive 98/79/EC on in-vitro diagnostic medical devices (IVD) stipulates marketing and post marketing surveillance of IVD in the European Economic Area. In cases of critical incidents and field safety corrective actions (FSCA) related to IVD manufacturers have to inform the responsible Competent Authorities (CA). In Germany the BfArM is responsible for most IVD (except few IVD serving for immune hematology, tissue typing and infection testing listed in Annex II falling into the responsibility of the Paul-Ehrlich-Institute (PEI)). In our study we analysed all notifications regarding IVD for point of care testing (POCT) of blood gases, hemoglobin and electrolytes regarding source of notification, type of product as well as frequency/type of product failure and corrective action performed by the manufacturers. Notifications related to metabolites (e. g. glucose, lactate) and coagulation parameters (e. g. International Normalised Ratio (INR)) on point of care analysers were not included in our study. Also systems serving for large series measurement of these parameters in laboratories only were not included. BfArM received 3325 notifications related to IVD within the observation period (begin 1999 – end 2011). Of these 55 were related to point of care analysers and consumables (reagents, tests, electrodes (sometimes part of the analyser)) for measurement of blood gases and hemoglobin and electrolytes included in our study. Predominantly reports were received from manufacturers (43). Minor numbers were received from users (7), other CAs (4) and other sources (1). Underlying root causes of product failures were identified in 49 cases (89.1 %). Most frequently these were software errors (12, mainly in analysers), errors in production and/or quality control (10), constructional faults (10) and analytical interferences (6). Further 4 cases (7.3 %) of product failures were caused by use errors. In 1 more case a product failure was excluded by the investigation of the manufacturer and in 1 further case the cause of product failure remained unclear. Corrective actions were performed by the manufacturers in 49 cases (89.1 %) mostly in cases of confirmed product failure. In 1 more case a corrective action was performed outside the German market because the product was not distributed in Germany. Most frequent corrective actions (multiple entries) for products already in the market were customer information (45, mandatory in cases of recalls) and recalls (32). Depending on the identified root causes of product failure preventive corrective actions were performed, most commonly software-updates (18, mostly analysers) as well as modifications in production and/or quality control (15), instructions for use (12) and product design (9). The obtained data characterise the most relevant causes of product failures in point of care systems for measurement of blood gases, hemoglobin and electrolytes demonstrating differences between analysers and consumables. Results also suggest that the European system for post marketing surveillance of IVD is a valuable tool to enhance product safety.