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MARKET SURVEILLANCE OF IN VITRO DIAGNOSTICS BY THE BFARM UNTIL END 2009 – HOW SAVE ARE PRODUCTS FOR THERAPEUTIC DRUG MONITORING?

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The European Directive 98/79/EC on in-vitro diagnostic medical devices (IVD) regulates the marketing and post market surveillance of IVD in the European Economic Area. In cases of incidents and field corrective actions the manufacturers have to inform the responsible Competent Authorities (CA). In Germany, the Federal Institute for Drugs and Medical Devices (BfArM) is the responsible CA for most IVD. In this study all notifications regarding IVD for therapeutic drug monitoring (TDM) between begin 1999 until end of 2009 were analysed. All notifications were analysed in respect to the source of notification, the product group, the underlying product defects and the corrective actions performed. In the observation period a total of 2369 notifications were received of which 50 were related to IVD for TDM included in this study (43 tests, calibrators, kits and control materials vs. 7 analysers). Reports were received from manufacturers (44), Competent Authorities (5) and users (1). In the group of tests the affected products were most frequently IVD for TDM of gentamicin (6), phenobarbital (5), drugs of abuse (5, except ethanol), vancomycin (3), cyclosporine (3) and tacrolimus (3). Investigations of the manufacturers were able to identify the underlying root causes of product failures in 39 cases (78.0 %) from which were 33 tests and 6 analysers. In 8 cases (16.0 %, all tests) the root cause remained unclear and in 3 cases (6.0 %, 2 tests, 1 analyser) a product failure was excluded. Product failures in tests, calibrators, kits and control materials were most commonly material defects (10), interferences (7), miss of specification (4) and production errors (4). In the analyser group product failures were predominantly caused by software errors (3) and errors in the instructions for use (2). Corrective actions were performed in 41 cases (82 %; 35 in tests, 6 in analysers) and were based on the underlying root cause of product failure. In the group of tests these were predominantly (multiple entries possible) customer information (35, mandatory in case of a recall), recalls (24), modifications in production or quality management (23), design changes (6), modifications of the instructions fore use (6), changes of the used raw materials (6) as well as modifications of the labelling (6). However, in the analyser group corrective actions were customer information (6), recalls (3), modifications of the instructions for use (3), software upgrade (2) and modifications in production or quality management (2). The obtained data demonstrate that there are strong differences in the type of product failures between analysers and tests. Tests are typically affected by material defects and interferences whereas analysers are prone to software errors and errors in the instruction for use. In consequence, there are also relevant differences of the corrective actions which depend on the underlying causes of product failure. The results and the experience since 1999 suggest that the system for post marketing surveillance of IVD is an established tool to enhance product safety even though the current system could be further optimised.