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MARKET SURVEILLANCE OF IN VITRO DIAGNOSTICS BY THE BFARM UNTIL END 2009 – HOW SAFE ARE PROFESSIONAL USE LABORATORY PRODUCTS FOR TUMOR DIAGNOSTICS?

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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 professionally used reagents (tests, calibrators, kits and control materials) for tumour diagnostics received by the BfArM between begin 1999 until end of 2009 were analysed. Notifications regarding the analysers on which these tests are performed, as well as notifications related to rapid tests (test strips), were not included as these products are based on a different technology or were marketed as lay use products, respectively. All notifications were analysed in respect to the source of notification, 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 tumour diagnostics included in this study. Reports were predominantly received from manufacturers (42), Competent Authorities (3) and other sources (4), whereas only one notification from a user was received. The affected products were most frequently IVD for determination of prostate specific antigen (PSA), human chorion gonadotropine (hCG, serving also for pregnancy testing), carcino embryonic antigen (CEA), α1-fetoprotein and CA 19-9. Investigations of the manufacturers were able to identify the underlying root causes of product failures in 36 cases (72.0 %). In 6 cases (12.0 %) the root cause remained unclear and in 5 cases and 3 cases (10.0 % and 6.0 %) a product failure was excluded or a user error was the underlying cause. Most common product failures were caused by material defects (9), manufacturing errors (9), interferences (4), miss of specification (4) and calibration errors (3). Corrective actions were performed by the manufacturers in 34 cases (68.0 %). Based on the underlying root causes of product failures these were predominantly (multiple entries possible) customer information (34, mandatory in case of a recall), recalls (26), modifications in production or quality management (26), design changes (4), modifications of the instructions for use (4) as well as cessation of product marketing (3). The obtained results and 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.