COMPANION DIAGNOSTICS - NEED FOR MORE REGULATION

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Companion diagnostics (CD, e. g. for tumor diagnostics) and corresponding medicinals are of increasing importance. CD were not subject of specific regulation in the “old” European Directive 98/79/EC but now are covered by the “new” regulation to be adopted. Here we demonstrate regulatory changes, CD approved by the FDA and CD which were subject of field safety corrective actions (FSCA) in Germany. CD were defined according the FDA definition and a list of FDA approved CD. Analysis of FSCA was based on publications between 2005 and 2015 on the BfArM homepage. The FDA list includes <30 CD, all except 1 for use in oncology (mostly HER-2 (10), EGFR (6), K-RAS (2), BRAF (2)). 11 FSCA (K-RAS (5, colorectal cancer), herceptin (4, breast cancer), EGFR (1, lung cancer) BRAF (1, melanoma)) were found for CD. In all cases manufacturers performed a recall. Only 5 tests were FDA approved. The number of FDA approved CD and CD affected by FSCA is small standing in contrast to their importance. Likely, a major number tests is not FDA approved, based on in-house testing or was not subject of a FSCA. This demonstrates the future importance of these tests and the need for regulation.