Postmarketing Safety Evaluation: Monitoring, Assessing, and Reporting of Adverse Drug Responses

Once a new drug is approved, it proceeds to market either with or without postmarketing evaluation requirements. While this represents the end of a long road, it is also the start of yet another. While careful work during development (both in animals and humans) serves to provide the tools to greatly reduce the potential safety issues around a new drug, it cannot totally eliminate them. One needs only to look at Table 1 to appreciate the history of market withdrawals due to safety issues in the modern era (1961–2001) or turn to Table 2 to verify that the problem is still present in the first decade of the twenty-first century and comparable to the past.

Tracking and continuing to evaluate the safety of a therapeutic agent once it is on the market represent a complex task. Manufacturers are legally required to collect, analyze, and report such data both nationally [by the U.S. Food and Drug Administration (FDA) and by equivalent organizations in other countries, but here the emphasis will be on the U.S. situation] and internationally

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