

Drug-Induced Liver Injury: Clinical Summary and Premarketing Evaluation

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Drug-induced liver injury (DILI) is a potential complication from medications that are in development and on the market. Underlying mechanisms for DILI have not been well elucidated. The spectrum of DILI ranges from mild (possibly leading to adaptation) to severe (fatal, or requiring liver transplantation). The diagnosis of DILI is mainly based on clinical evidence by establishing the temporal relationship between the drug intake and subsequent liver injury after excluding other differential diagnoses. From the regulatory and pharmaceutical points of view, since drug-induced hepatotoxicity has been the most common single cause for drug withdrawal from the market due to safety concerns, it is crucial to detect possible drugs that can cause severe DILI early in the stage of new drug development. The recent concept paper by U.S. FDA on premarketing evaluation of DILI and the implementation of drug relief for severe DILI in Taiwan will be discussed in this presentation.

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