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New Drug Approval Procedure in Different Countries: A Review

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Abstract:Today, the regulatory requirements for approval of a new drug in the various countries of the world are quite different. To develop one single regulatory approach for marketing authorization application (MAA) of a new drug product for various countries is utmost difficult task- especially for companies with global activities.

Therefore, it is very important to know in detail the regulatory requirements in each country where an MAA should be submitted to establish a suitable regulatory strategy before the submission in order to avoid any major difficulties. The new drug approval is of two phase process, clinical trials phase & Marketing authorization of drug. The review article is based on the procedures for drug approval in different countries like India, USA, Australia, China, Turkey, Canada and European countries.

Keywords:New drug approval, Drug Approval procedure, Approval stages, USFDA.

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