

# **A review of basic and clinical researches on musculoskeletal shockwave therapy in Japan. Why it has not been approved?**

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Although musculoskeletal shockwave therapy has now spread all over the world, it has not still approved by the Ministry of Health, Labour and Welfare in Japan. Single blind clinical trial had finished in 1998, but the positive results did not accepted because of some accusations such as insufficiency of the protocol for control study, which had been permitted by the Ministry itself before beginning of the clinical study, and so on. After the FDA approval in 2000, some manufacturers applied to the Japanese government for approval of shockwave therapy using results of the FDA study. These applications had been under consideration until 2003, however, approval system in Japan completely changed in 2004, unfortunately. Japanese government newly established Pharmaceuticals and Medical Devices Agency for judging and all the process of judgment was restarted.

In spite of these misfortune, musculoskeletal shockwave therapy have been developing in Japan since 1994, mainly in basic field. Purpose of this presentation is to introduce basic and clinical researches on musculoskeletal shockwave therapy uniquely developing in Japan.