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Challenges to Establishment of Pharmacovigilance System - Lessons from the PPA Issues on August 2004

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All the medicines have benefits of preventing and/or treating diseases, as well as inevitably risks such as adverse reactions. With this reason, medicines are allowed to be marketed only after being reviewed the safety and efficacy with the results of clinical trials, etc.. And that's why safety information monitoring is continuously performed.

The Phenylpropanolamine(PPA) issues on August '04, apart from its detailed refutation, became an importance opportunity to call not only regulatory authority but also health professionals and consumers' attention to the pharmacovigilance system in Korea.

The safety issue of PPA which has been used for 40 years all over the world has been discussed from around 1990. And then on 2000 FDA requested industry to stop the marketing of PPA-containing products after reviewing the Yale University's report on the safety of PPA . The Republic of Korea, with reference to the study result of Yale University, decided to perform its own epidemiology study on safety of the low dose of PPA-containing cold remedies whose safety risk were not clear, while withdrawing all the PPA containing appetite-suppressant drugs from the market. After about 2 years and 2 months, the study result was submitted to KFDA on June, 2004. And KFDA carefully reviewed it and concluded to prohibit the use of the relevant products and withdraw all the PPA-containing cold remedies.

But the social agitation on the government's action on PPA may attribute its cause to illusive overconfidence on the safety of drugs as well as humble democracy which doesn't count on professional opinions of experts. And this situation may be called an example which directly showed the lack of people's awareness on the safety management of our society.

Our government has enacted and operated the regulations on the adverse drug monitoring since the early of 1990 and promoted it diversely, such as establishing reporting system through web-site of KFDA and giving a lecture on ADRs to the pharmacists. However, the number of reports is only about 200 ~ 300 cases which is very few compared with 250,000 cases of US and 20,000 cases of Japan. To activate the ADR monitoring, the high consciousness and cooperation of health professionals, such as medical doctors and pharmacists, are essential.

Therefore, KFDA is pursuing to, on shot-term basis, continuously and actively promote and educate not only health professionals but also consumers on the ADR. Also it plans to establish infrastructure for properly performing drug safety information management, such as establishing "the Korea Drug Information Institute" and supplement of personnels in need.

In addition, through this opportunity, I'd like to explain the government's plans to improve the regulation and system on ADR monitoring centering around the actions taken on PPA.