[S1-4] [10/10/2003(Fri) 13:30-14:00/ Grand Ballroom 102]

Modernization of Review Process for Generic Drug Products in Korea

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Recently, Korean Food and Drug Administration (KFDA) has been attempting to modernize the review processes for generic drug products. Obviously, the modernization effort will lead to harmonize the guidelines in the process to the internationally acceptable level. In general, the Korean version of abbreviated new drug application (ANDA) consisted of similarly to those in developed countries (*viz,* specifications for bulk drug/preparation, bioequivalence, and stability); However, there exists a significant gap in the sophistication of the guidelines between the Korean version and those in the other countries. Therefore, in this presentation, the guidelines in ANDA from Korea, US and Japan will be compared and identified the primary differences, and, ultimately, I will propose the direction of change for the submission. According to the guidelines for ANDA in the US, manufacturing and monitoring of drug/preparation consisted of the majority of the submission, followed by bioequivalence and stability testings. Regarding the submission for information relevant to specifications of bulk drug/preparations, detailed guidelines have not been published for the Korean version of ANDA, suggesting that step by step guideline has to be formulated for KFDA. According to guideline published, Korean, US and Japanese guidelines for bioequivalence testing appear quite similar generally, while there exists subtle differences. The most notable difference between the countries was the SUPAC (scale-up and post approval changes) guidelines in the US. The SUPAC guideline specifies the extent of changes in the additives in the formulation for the human study. While the scientific validity of the SUPAC guideline is still not clear, the prevention of potential bioavailability problems appears prudent. Therefore, Korean version of SUPAC guideline appears necessary for the further enhancement of qualities of drug products. The other notable difference in the three bioequivalence guidelines was that, in Japan, the necessity of human study is determined according to a systematic dissolution testing of drug products. It is generally believed that dissolution testing may be readily carried out while the human study takes a considerable amount of time and man-power. It appears, therefore, the Japanese version of the bioequivalence testing is scientifically valid and, thus, an useful approach. Since there exist certain advantages in the guidelines of developed countries (e.g., SUPAC guideline in US; a systematic dissolution testing in Japan), the differences have to be taken into consideration for the future revision of guidelines for ANDA submission in Korea.