Current Status of Drug Master Files (DMF)

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Korea Food and Drug Administration (hereafter, KFDA) employed DMF system to ensure the quality assurance of drug substances as of Jul. 1. 2002. According to this system, any person who intends to manufacture and/or import the drug substances that the Commissioner of KFDA designates to register should submit a comprehensive dossier on manufacturing and quality control which includes manufacturing facility, manufacturing process, raw material at each process, in - process control, residual solvents, impurities, packaging materials and stability by item. Pharmaceutical manufacturers should not use(import) other substances than those which were reviewed and notified as an appropriate one by KFDA.

At the beginning time in July 2002, the scope of drug substances to which the Guideline had been applied was limited to the active pharmaceutical ingredient of "new chemical entity" to consider the public health environment, manpower problems in administration and the preparatory period for the company. As of Sep. 1, 2005, KFDA extended the DMF designation to 77 substances including 'Gliclazide (Diabetes drug)" which are nationally used in abundance.

So far, the status of "New chemical entity" and 77 substances which were submitted, evaluated and posted is as follows :

(Oct. 30. 2005.)

Category	Submit	Notification	Withdrawal or rejected	Under review	Remark
New chemical entity	38	18 (pre-approval site inspection 11)	4	16	
77 substances	633	450 (pre-approval site inspection 170)	135	48	

For the reference, 「DMF Inspection Teams」 has been set up so as to facilitate the efficient inspection given time line for 77 substances. This Squad has been consisted of the persons from Drug Safety Bureau, Drug Evaluation Division, National Institute of Toxicological Research or regional agencies. The 181 substances (Korean: 26 sites, Foreign: 63 sites) have been inspected from April 2005 to August 2005 among which 16 sites were appropriate, 57 sites need to supplement, 16 sites were not appropriate. Especially, total 212 items made in China and .India were submitted and only 123 items were posted as an appropriate substance so that 58% was posted. 450 items made in Korea were submitted and 164 items were posted so that 36.4% was posted.

The rate of substance independence in Korea had been no more than 10% and most of substances had been imported till 2002. After the employment of DMF system, however, it has been assessed that this system has contributed to cut off low price and low quality of substances and established for the employment of good quality and safety substances made in Korea.

Based on this great success, KFDA will expend the DMF substances further as soon as possible for the early settlement of this system and the quality improvement of Korean pharmaceutical products. In the future, KFDA are carrying forward with a manpower reinforcement plan to secure experts for the inspection and completing to inspect 287 items (179 sites) by 2006, the subjects of the post-approval site inspection, out of 450 items that were already notified.