ANNOUNCEMENT 12/10/MDS-AN003

SUBJECT: Publication of Marketing Authorization application fees and review times.

ADDRESSEES: Manufacturers of medical devices (both local and overseas) and authorised representatives for both local and overseas manufacturers

Marketing Authorization application fees and review times will be as follow:

Table for Medical Device Marketing Authorization (MDMA) Processing Fees

Fee Groups	The Basis of the application for SFDA Marketing Authorization	Three years or less (SR)	More than three years (SR)	Lead time (Working Days)
FG (1)	ALL CLASS I / General IVD (other)/ Exempt IVD (TGA)	15000*	N/A	35
FG (2)	ALL CLASS II / CLASS IIa / Self-test IVD, Listable IVD	19000	21000	35
FG (3)	CLASS IIb / CLASS III (CA,PAL) /Annex II List B (IVD)	21000	23000	35
FG (4)	All other CLASS III/ CLASS IV / AIMD / Annex II List A (IVD) / Registrable IVD	23000	25000	35

Notes:

* For Class I, the Medical Device Marketing Authorisation issued by SFDA will be valid for Three (3) Years

• For all other classes, the Medical Device Marketing Authorisation issued by SFDA will be valid for the remaining validity of the original license or for Three (3) years for license with undefined validity.