Appendix 7:

Technical Documents for the Application of Drug Review and Registration of Bio-Pharmaceutical Products

Documents (Note4)	Origin, discovery process and uses in other countries			Physicochemical properties, testing methods and specifications			Stability study report	Non-clinical safety study report								Pharmacological effect		Absorption, distribution, metabolism, excretion, BA/BE study reports							Clinical trial report		Other Data
	Origin and the discovery process	Uses in other countries	Comparison of properties	Structure	Physicochemical properties	Testing specifications and methods		Single dose toxicity	Repeated dose toxicity (3 months)	Repeated dose toxicity (6 months)	Reproduction toxicity	Dependency	Antigenicity	Genotoxicity	Carcinogenicity	Local tolerance	Evidence of effectiveness	General pharmacology	absorption	Distribution	Metabolism	Excretion	BA	BE	Clinical trials	Medical journals	
Genetic Engineering drugs	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	△	○	○	○	△	△	○	○	Note 1
Bio-similars	○	○	○	○	○	○	○	○	○	○	×	×	○	×	×	○	○	○	△	○	○	○	△	△	○	○	Note 1
Vaccines	○	○	○	△	△	○	○	○	△	△	△	×	○	△	×	△	○	×	△	△	△	△	△	△	○	○	Note 2
Drugs derived from human blood	△	△	△	×	△	○	○	△	×	×	×	×	△	×	×	×	△	△	×	×	×	×	×	×	○	○	Note 3

Allergen drugs	△	○	△	╳	△	○	○	△	△	╳	╳	╳	○	╳	╳	△	△	╳	△	△	△	△	△	△	△	△	--
Other	○	○	○	△	△	○	○	○	△	△	△	△	○	△	△	△	○	△	△	△	△	△	△	△	○	○	--

○: submission is a must; ╳: submission is not necessary; △: submission is on a case-by-case basis

Note

1 The application of genetic engineering drugs should include the following information: the structure and properties of expression vector, the properties of the host, a description of the master cell bank (MCB) and the manufacture working cell bank (MWCB) and their vectors' stability, product harvest and purification process.

2 The manufacturing and control of vaccines should comply with the "Seed Lot System". This includes taking samples in each stage throughout the manufacturing process and completing every test before packing in smaller sizes. Tests should be conducted in stages of seed strain, master seed lot, manufacturing working cell bank, cell culture medium, fermentation product, purification products, liquid before packing into smaller sizes and final products. There should be a detailed description of the purification method.

3 The application of drugs derived from human blood should include information on the sources and specifications of blood (each blood bag should go through tests of HBsAg, anti-HCV, anti-HIV-I and II). The validation documents of virus inactivation and removal processes should also be submitted. Plasma pool should be tested by applying the nucleic acid amplification technology (NAT). The results should at least show negative in the NAT of HCV, HIV and HBV. If the NAT method used has not yet been certified by the Taiwanese authority, the applicant should follow the guideline on the review and registration of other products and submit related documents to justify the testing specifications, methods and sensitivity, etc. The central health competent authority may consider the regulations in other countries and increase new testing items and requirements. The manufacturing and control documents should include testing on samples taken from each stage before packing in smaller sizes. Tests should be conducted in stages of blood bag, plasma pool, purification products, liquid before repackaging and final products.

4 Application dossiers shall be submitted according to the Common Technical Document (CTD) format.