Chapter 18A

EQUITY SECURITIES

BIOTECH COMPANIES

Scope

This Chapter sets out additional listing conditions, disclosure requirements and continuing obligations for Biotech Companies that seek to list on the basis that they are unable to satisfy either the profit test in rule 8.05(1), the market capitalisation/revenue/cash flow test in rule 8.05(2), or the market capitalization/revenue test in rules 8.05(3).

Issuers are encouraged to contact the Exchange if they envisage any difficulties in complying fully with the relevant requirements.

DEFINITIONS AND INTERPRETATION

18A.01 For the purposes of this Chapter unless otherwise stated or the context otherwise requires the following terms have the meanings set out below:—

"Approved Product"	a Biotech Product which has been approved for commercialisation by a Competent Authority.
"Biotech"	the application of science and technology to produce commercial products with a medical or other biological application.
"Biotech Company"	A company primarily engaged in the research and development, application and commercialisation of Biotech Products.
"Biotech Product"	Biotech products, processes or technologies
"Competent Authority"	the US Food and Drug Administration, the China Food and Drug Administration, the European Medicines Agency. The Exchange may, at its discretion, recognise another national or supranational authority as a Competent Authority for the purposes of this Chapter in individual cases (depending on the nature of the Biotech Product).

"Core Product"	A Regulated Product that (alone or together with other Regulated Products) forms the basis of a Biotech Company's listing application under this chapter.
"Cornerstone Investor"	An investor in the initial public offering of a new applicant's shares to whom offer shares are preferentially placed with a guaranteed allocation irrespective of the final offer price, usually for the purpose of signifying that the investor has confidence in the financial condition and future prospects of the new applicant.
"Regulated Product"	A Biotech Product that is required by applicable laws, rules or regulations to be evaluated and approved by a Competent Authority based on data derived from clinical trials (i.e. on human subjects) before it could be marketed and sold in the market regulated by that Competent Authority.

CONDITIONS FOR LISTING OF BIOTECH COMPANIES

18A.02 An applicant that has applied for listing under this Chapter must, in addition to satisfying the requirements of this Chapter, also satisfy the requirements of Chapter 8 (other than rules 8.05, 8.05A, 8.05B and 8.05C).

18A.03 An applicant that has applied for listing under this Chapter must:—

(1) demonstrate that it is both eligible and suitable for listing as a Biotech Company;

(2) have an initial market capitalisation at the time of listing of at least HK$1,500,000,000;

(3) have been in operation in its current line of business for at least two financial years prior to listing under substantially the same management; and

(4) ensure that it has available sufficient working capital to cover at least 125% of the group's costs for at least 12 months from the date of publication of its listing document (after taking into account the proceeds of the new applicant's initial listing). These costs must substantially consist of the following:—

(a) general, administrative and operating costs (including any production costs); and

(b) research and development costs.

Note 1: The Exchange would expect that the issuer would use a substantive portion of the proceeds from its initial listing to cover these costs.

Note 2: Capital expenditures do not need to be included in the calculation of working capital requirements for the purpose of this rule. However, where capital expenditures are financed out of borrowings, relevant interest and loan repayments must be included in the calculation. For the avoidance of doubt, Biotech Companies must include research and development costs, irrespective of whether they are capitalised, in the calculation of working capital requirements for the purpose of this rule.

CONTENTS OF LISTING DOCUMENTS FOR BIOTECH COMPANIES

18A.04 In addition to the information set out in Appendix D1A, a Biotech Company must disclose in its listing document:—

(1) its strategic objectives;

(2) the details of each Core Product, including:

(a) a description of the Core Product;

(b) details of any relevant regulatory approval required and/or obtained for each Core Product;

(c) summary of material communications with the relevant Competent Authority in relation to the its Core Product(s) (unless such disclosure is not permitted under applicable laws or regulations, or the directions of the Competent Authority);

(d) the stage of research and development for each Core Product;

(e) development details by key stages and its requirements for each Core Product to reach commercialisation, and a general indication of the likely timeframe, if the development is successful, for the product to reach commercialisation;

(f) all material safety data relating to its Core Product(s), including any serious adverse events;

(g) a description of the immediate market opportunity of each Core Product if it proceeds to commercialisation and any potential increased market opportunity in the future (including a general description of the competition in the potential market);

(h) details of any patent(s) granted and applied for in relation to the Core Product(s) (unless the applicant is able to demonstrate that such disclosure would require the applicant to disclose highly sensitive commercial information), or an appropriate negative statement;

(i) in the case of a Core Product which is biologics, disclosure of planned capacity and production related technology details; and

(j) to the extent that any Core Product is in-licensed, a clear statement of the issuer's material rights and obligations under the applicable licensing agreement;

(3) a statement that no material unexpected or adverse changes have occurred since the date of issue of the relevant regulatory approval for a Core Product (if any). Where there are material changes, these must be prominently disclosed;

(4) a description of Approved Products (if any) owned by the applicant and the length of unexpired patent protection period and details of current and expected market competitors;

(5) details of the Biotech Company's research and development experience, including:

(a) details of its operations in laboratory research and development;

(b) the collective expertise and experience of key management and technical staff; and

(c) its collaborative development and research agreements;

(6) details of the relevant experience of the Biotech Company's directors and senior management in the research and development, manufacturing and commercialisation of Biotech Products;

(7) the salient terms of any service agreements between the applicant and its key management and technical staff;

(8) measures (if any) that the applicant has in place to retain key management or technical staff (for example incentivisation arrangements and/or non-compete clauses), and the safeguards and arrangements that the applicant has in place, in the event of the departure of any of its key management or technical staff;

(9) a statement of any legal claims or proceedings that may have an influence on its research and development for any Core Product;

(10) disclosure of specific risks, general risks and dependencies, including:

(a) potential risks in clinical trials;

(b) risks associated with the approval process for its Core Product(s); and

(c) the extent to which its business is dependent on key individuals and the impact of the departure of key management or technical staff on the applicant's business and operations;

(11) if relevant and material to the Biotech Company's business operations, information on the following:—

(a) project risks arising from environmental, social, and health and safety issues;

(b) compliance with host country laws, regulations and permits, and payments made to host country governments in respect of tax, royalties and other significant payments on a country by country basis;

(c) its historical experience of dealing with host country laws and practices, including management of differences between national and local practice; and

(d) its historical experience of dealing with the concerns of local governments and communities on the sites of its research and trials, and relevant management arrangements;

(12) an estimate of cash operating costs, including costs relating to research and development and clinical trials incurred in the development of the Core Product and costs associated with:—

(a) workforce employment;

(b) direct production costs, including materials (if it has commenced production);

(c) research and development;

(d) product marketing (if any);

(e) non-income taxes, royalties and other governmental charges (if any);

(f) contingency allowances; and

(g) any other significant costs; and

Note: A Biotech Company must:

- *set out the components of cash operating costs separately by category;*
- *explain the reason for any departure from the list of items to be included under cash operating costs; and*
- *discuss any material cost items that should be highlighted to investors.*

(13) if the applicant has obtained an expert technical assessment and where relevant and appropriate, include such assessment in its listing document.

18A.05 A Biotech Company must, in respect of each Core Product, prominently disclose to investors a warning that the relevant Core Product may not ultimately be successfully developed and marketed.

18A.06 A Biotech Company must comply with rule 4.04 modified so that references to "three financial years" or "three years" in that rule shall instead reference to "two financial years" or "two years", as the case may be.

CORNERSTONE INVESTORS

18A.07 A Biotech Company seeking an initial listing under this chapter must, in addition to meeting the requirements of Rule 8.08(1), ensure that a portion of the total number of its issued shares with a market capitalisation of at least HK$375 million are held by the public at the time of its initial listing. Any shares allocated to a Cornerstone Investor and any shares subscribed by existing shareholders of the Biotech Company at the time of listing shall not be considered as held by the public for the purpose of this rule 18A.07.

CONTINUING OBLIGATIONS

Disclosure in Reports

18A.08 A Biotech Company must include in its interim (half-yearly) and annual reports details of its research and development activities during the period under review, including:

(1) details of the key stages for each of its Core Products under development to reach commercialisation, and a general indication of the likely timeframe, if the development is successful, for the Core Product to reach commercialisation;

(2) a summary of expenditure incurred on its research and development activities; and

(3) a prominently disclosed warning that a Core Product may not ultimately be successfully developed and marketed.

Note: Details to be disclosed should be in line with those disclosed in the listing document of the Biotech Company under rules 18A.04 and 18A.05.

Sufficient Operations

18A.09 Where the Exchange considers that a Biotech Company listed under this chapter fails to comply with rule 13.24, the Exchange may suspend dealings or cancel the listing of its securities under rule 6.01. The Exchange may also under rule 6.10 give the relevant issuer a period of not more than 12 months to re-comply with rule 13.24. If the relevant issuer fails to re-comply with rule 13.24 within such period, the Exchange will cancel the listing.

Material Changes

18A.10 Without the prior consent of the Exchange, a Biotech Company listed under this chapter must not effect any acquisition, disposal or other transaction or arrangement or a series of acquisitions, disposals or other transactions or arrangements, which would result in a fundamental change in the principal business activities of the relevant issuer as described in the listing document issued at the time of its application for listing.

Stock Marker

18A.11 The listed equity securities of a Biotech Company listed under this chapter must have a stock name that ends with the marker "B".

Dis-application of rules 18A.09 to 18A.11

18A.12 Upon application by the listed Biotech Company and demonstration that it is able to meet the requirements of rule 8.05, rules 18A.09 to 18A.11 do not apply to a Biotech Company listed under this chapter.