1. **Purpose**

1.1 This letter provides guidance on the factors that the Exchange will take into account when considering whether an applicant is suitable for listing under Chapter 18A of the Main Board Listing Rules and, after its listing, the application of certain rules on notifiable transactions and connected transactions to such issuers listed under Chapter 18A of the Main Board Listing Rules.

2. **Relevant Listing Rules**

2.1 Main Board Listing Rule 14.20 states that the Exchange may, where any of the calculations of the percentage ratios produces an anomalous result or is inappropriate to the sphere of activity of the listed issuer, disregard the calculation and substitute other relevant indicators of size, including industry specific tests. The listed issuer must provide alternative tests which it considers appropriate to the Exchange for consideration.

2.2 Main Board Listing Rule 18A.03(1) states that an applicant that has applied for listing under Chapter 18A of the Main Board Listing Rules must demonstrate to the Exchange’s satisfaction that it is both eligible and suitable for listing as a Biotech Company.

3. **Suitability Criteria**

3.1 An applicant applying for listing under Chapter 18A must meet the definition of a Biotech Company as defined in that chapter.

3.2 A Biotech Company that does not meet either the profit test in Main Board Listing Rule 8.05(1), the market capitalisation/revenue/cash flow test in Main Board Listing
Rule 8.05(2) or the market capitalisation/revenue test in Main Board Listing Rule 8.05(3) (together, the “Financial Eligibility Tests”) for listing on The Stock Exchange of Hong Kong Limited could be permitted to list under Chapter 18A if it can demonstrate the following features:

(a) the Biotech Company must have developed at least one Core Product beyond the concept stage. The Exchange would consider a Core Product to have been developed beyond the concept stage if it has met the developmental milestones specified for the relevant type of product (see paragraph 3.3 below);

(b) it must have been primarily engaged in research and development (“R&D”) for the purposes of developing its Core Product(s);

(c) it must have been engaged with the R&D of its Core Product(s) for a minimum of 12 months prior to listing (and, in the case of a Core Product which is in-licensed or acquired from third parties, the applicant must be able to demonstrate R&D progress since the in-licensing/acquisition);

(d) it must have as its primary reason for listing the raising of finance for R&D to bring its Core Product(s) to commercialisation;

(e) it must have registered patent(s), patent application(s) and/or intellectual property in relation to its Core Product(s);

(f) if the applicant is engaged in the R&D of pharmaceutical (small molecule drugs) products or biologic products, it must demonstrate that it has a pipeline of those potential products; and

(g) it must have previously received meaningful third party investment (being more than just a token investment) from at least one Sophisticated Investor at least six months before the date of the proposed listing (which must remain at IPO). This factor is intended to demonstrate that a reasonable degree of market acceptance exists for the applicant’s R&D and Biotech Product. Where the applicant is a spin-off from a parent company, the Exchange may not require compliance with this factor if the applicant is able to otherwise demonstrate to the Exchange’s satisfaction that a reasonable degree of market acceptance exists for its R&D and Biotech Product (for example, in the form of collaboration with other established R&D companies).

(i) The Exchange will assess whether an investor is a “Sophisticated Investor” for the purpose of applications for listing under Chapter 18A on a case by case basis by reference to factors such as net assets or assets under management, relevant investment experience, and the investor’s knowledge and expertise in the relevant field.
For this purpose, the Exchange would generally consider the following as examples, for illustrative purposes only, of types of Sophisticated Investor:

(1) a dedicated healthcare or Biotech fund or an established fund with a division/department that specialises or focuses on investments in the biopharmaceutical sector;

(2) a major pharmaceutical/healthcare company;

(3) a venture capital fund of a major pharmaceutical/healthcare company; and

(4) an investor, investment fund or financial institution with minimum assets under management of HK$1 billion.

(ii) The Exchange will assess whether a third party investment is a meaningful investment in the circumstances on a case by case basis by reference to the nature of the investment, the amount invested, the size of the stake taken up and the timing of the investment. As an indicative benchmark the following investment amount will generally be considered as a “meaningful investment”:

(1) for an applicant with a market capitalisation between HK$1.5 billion to HK$3 billion, an investment of not less than 5% of the issued share capital of the applicant at the time of listing;

(2) for an applicant with a market capitalisation between HK$3 billion to HK$8 billion, an investment of not less than 3% of the issued share capital of the applicant at the time of listing; and

(3) for an applicant with a market capitalisation of more than HK$8 billion, an investment of not less than 1% of the issued share capital of the applicant at the time of listing.

3.3 For the purpose of paragraph 3.2(a) above, the Exchange would consider the following to demonstrate that a Regulated Product has developed beyond the concept stage.

(a) Pharmaceutical (small molecule drugs)

(i) In the case of a Core Product that is a new pharmaceutical (small molecule drug) product, the applicant must demonstrate that it has
completed Phase I\textsuperscript{1} clinical trials and that the relevant Competent Authority has no objection for it to commence Phase II\textsuperscript{2} (or later) clinical trials.

(ii) In the case of a Core Product that is a pharmaceutical (small molecule drug) product which is based on previously approved products (for example, the 505(b)(2) application process of the US Food and Drug Administration (“FDA”) in the US), the applicant must demonstrate that it has successfully completed at least one clinical trial conducted on human subjects, and the relevant Competent Authority has no objection for it to commence Phase II (or later) clinical trials.

(b) Biologics

(i) In the case of a Core Product that is a new biologic product, the applicant must demonstrate that it has completed Phase I clinical trials and the relevant Competent Authority has no objection for it to commence Phase II (or later) clinical trials.

(ii) In the case of a Core Product that is a biosimilar, the applicant must demonstrate that it has completed at least one clinical trial conducted on human subjects, and the relevant Competent Authority has no objection for it to commence Phase II (or later) clinical trials to demonstrate bio-equivalency.

(c) Medical devices (including diagnostics)

In the case of a Core Product that is a medical device (which includes diagnostic devices), the applicant must demonstrate that:

(i) the product is categorised as Class II medical device (under the classification criteria of the relevant Competent Authority) or above;

(ii) it has completed at least one clinical trial on human subjects (which will form a key part of the application required by the Competent Authority or the Authorised Institution\textsuperscript{3}); and

\textsuperscript{1} Clinical trials on human subjects categorised as Phase I clinical trials by the FDA (or an equivalent process regulated by another Competent Authority). Where the applicant is conducting a combined clinical trial (for example a combined Phase I/Phase II clinical trial) the applicant will need to demonstrate to the Exchange’s satisfaction that the safety profile of the combined clinical trial is at least equivalent to the completion of Phase I clinical trials.

\textsuperscript{2} Clinical trials on human subjects categorised as Phase II clinical trials by the FDA (or an equivalent process regulated by another Competent Authority)

\textsuperscript{3} An institution, body or committee duly authorised or recognised by, or registered with, a Competent Authority or the European Commission for conducting, assessing and supervising clinical trials in the
(iii) either the Competent Authority or the Authorised Institution has endorsed or not expressed objection for the applicant to proceed to further clinical trials; or the Competent Authority (or, in the case of member(s) of the European Commission, an Authorised Institution) has no objection for the applicant to commence sales of the device.

3.4 Other Biotech Products

The Exchange will consider Biotech Products which do not fall into the categories set out in paragraph 3.3 on a case by case basis to determine if an applicant has demonstrated that the relevant Biotech Product has been developed beyond the concept stage by reference to, amongst other things, the factors described above in paragraph 3.3, and whether there is an appropriate framework or objective indicators for investors to make an informed investment decision regarding the listing applicant. A determination to accept such a listing application would be a modification that may only be made with the consent of the Securities and Futures Commission under Main Board Listing Rule 2.04. If the applicant is determined to be eligible for listing under Chapter 18A, references in this guidance letter and in Chapter 18A to “Core Products” shall be taken as referring to the Biotech Product of the applicant in question.

3.5 Applicants should note that that the factors set out in this section 3 are neither exhaustive nor binding and the Exchange will take into account all relevant circumstances in its assessment of the suitability of the applicant for listing.

4. Ownership continuity of a new applicant that is a Biotech Company

4.1 The Exchange will review any change in ownership of the applicant in the 12 months prior to the date of the listing application in assessing the suitability of the applicant for listing.

5. Subscription of shares by existing shareholders

5.1 Biotech Companies listed under Chapter 18A are expected to have significant ongoing funding needs in order to develop their Core Product to commercialisation. Existing investors in a Biotech Company are likely to have subscribed for shares in the company on the basis of their confidence in the company’s prospects, and may wish to be able to continue to participate in the company’s fundraisings to prevent a dilution to their shareholding. Historically, in the US, a significant majority of existing shareholders at IPO will continue to participate in the issuer’s fundraisings post-IPO.

relevant clinical fields. The Exchange may, at its discretion, recognise another institution, body or committee as an Authorised Institution on a case by case basis.
5.2 Given the likely significant funding needs of Biotech Companies and the importance of existing shareholders in meeting the funding needs of these companies, the Exchange permits existing shareholders to participate in the IPO of a Biotech Company provided that the issuer complies with Main Board Listing Rules 8.08(1) and 18A.07 in relation to shares held by the public.

6. Calculation of percentage ratios

6.1 Since Biotech Companies listed under Chapter 18A are not required to meet any of the Financial Eligibility Tests at the time of listing, the application of the revenue ratio and the profit ratio to any proposed transaction that these issuers propose to undertake may not be appropriate in some cases.

6.2 The Exchange may exercise its discretion under Rule 14.20 to disregard the revenue ratio and profit ratio for Biotech Companies listed under Chapter 18A and consider other relevant indicators of size, including industry specific tests suggested by the issuer, on a case by case basis. The listed issuer must provide alternative tests which it considers appropriate to the Exchange for consideration.

7. Accountants’ report

Biotech Companies applying for a listing under Chapter 18A with an accountants’ report covering two financial years are reminded that they must apply for a certificate of exemption from the relevant disclosure requirements under the Third Schedule of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong).