HKEX GUIDANCE LETTER
HKEX-GL92-18 (April 2018) (Updated in October 2019 and April 2020)

Subject	Suitability for Listing of Biotech Companies
Listing Rules and Regulations	**Main Board Listing Rules 9.09, 14.20 and 18A.03(1), and Practice Note 18 to Main Board Listing Rules**
Related Publications	**Guidance Letter HKEX-GL43-12 – Guidance on Pre-IPO investments ("GL43-12")** **Guidance Letter HKEX-GL85-16 – Guidance on Placing to connected clients, and existing shareholders or their close associates, under the Rules ("GL85-16")** **Guidance Letter HKEX-GL107-20 – Guidance on Disclosure in listing documents for Biotech Companies ("GL107-20")**
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Important note: *This letter does not override the Listing Rules and is not a substitute for advice from qualified professional advisers. If there is any conflict or inconsistency between this letter and the Listing Rules, the Listing Rules prevail. You may consult the Listing ~~Department~~Division on a confidential basis for an interpretation of the Listing Rules, or this letter. Unless otherwise specified, defined terms in the Listing Rules shall have the same meanings in this letter.*

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 ("**Chapter 18A**") 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 where any calculation of the percentage ratio produces an anomalous result or is inappropriate to the sphere of activity of the listed issuer, the listed issuer may apply to the Exchange to disregard the calculation and /or apply other relevant indicators of size, including industry specific test(s). The listed issuer must seek prior consent of the Exchange if it wishes to apply this rule and must provide alternative test(s) which it considers appropriate to the Exchange for consideration. The Exchange may also require the listed issuer to apply other

size test(s) that the Exchange considers appropriate.

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~~in R&D of its Core Product(s) for a minimum of 12 months prior to listing ~~(and, .~~ Non-exhaustive examples include the following:

(i) 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~~);~~. For example, the applicant's in-licensed or acquired products (1) progressed from preclinical stage to clinical stage, (2) progressed from one clinical phase to the next phase of clinical trial, or (3) obtained regulatory approval from the Competent Authority to market the Core Product; and

(ii) in the case of a Core Product which has been commercialised in a given market for specified indication(s) and the Biotech Company intends to apply a portion of the listing proceeds to, for example, (1) expand the indications of the commercialised Biotech Product, or (2) launch it in another market, the Exchange would expect further R&D expended on the Core Product in connection with the clinical trials required by the Competent Authority to either bring the Core Product for (1) a new indication; or (2) commercialisation in a new regulated market ***(Added in***

April 2020);

~~(c)~~(d) it must have as its primary reason for listing ~~the~~ raising ~~of finance~~funds for R&D to bring its Core Product(s) to commercialisation~~;~~. For Biotech Companies that develop medical devices which have a short development cycle, the Exchange may take into account these Biotech Companies' business plan and development stage of the pipeline products such that they may allocate a portion of listing proceeds to, for example, set up production facilities that will be primarily used for the manufacturing of Core Product(s) to bring it to commercialisation, and establish sales, marketing and medical teams to commercialise its Core Product(s) ***(Added in April 2020)***;

~~(d)~~(e) it must have registered patent(s), patent application(s)[1] ~~and~~ 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] For registered patents and applications, Rule 18A.04(2)(h) requires a Biotech Company to disclose in its listing document details of any patent(s) granted and applied for in relation to the Core Product(s) (unless the applicant is able to demonstrate to the satisfaction of the Exchange that such disclosure would require the applicant to disclose highly sensitive commercial information), or an appropriate negative statement ***(Added in April 2020)***.

(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[~~1~~2] clinical trials and that the relevant Competent Authority has no objection for it to commence Phase II[~~2~~3] (or later) clinical trials.

[2] 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.

[3] Clinical trials on human subjects categorised as Phase II clinical trials by the FDA (or an equivalent process regulated by another Competent Authority).

(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[3] (or later) clinical trials.

(iii) For an in-licensed or acquired Core Product, the Exchange expects the Biotech Company to complete at least one clinical trial regulated by the relevant Competent Authority on human subjects since the in-licensing or acquisition. If the applicant has not completed at least one clinical trial for the in-licensed or acquired Core Product, the Exchange will evaluate why no clinical trial has been completed and whether substantive R&D work and process(es) equivalent to the completion of one clinical trial on human subjects have been performed by the Biotech Company. The Exchange will not consider any administrative process as substantive R&D work and process(es) (***Added in April 2020***).

(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[2] clinical trials and the relevant Competent Authority has no objection for it to commence Phase II[3] (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.

(iii) For an in-licensed or acquired Core Product, the Exchange has the same expectation as set out in paragraph 3.3(a)(iii) above ***(Added in April 2020)***.

(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[34]); and

(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.

(a) The Exchange will categorise a Biotech Product as it is categorised by its Competent Authority. If a Biotech Product is regulated as a pharmaceutical, biologics, or medical device, a Biotech Company cannot re-classify such products as "Other Biotech Product" because it is unable to fulfil any of the requirements of the relevant category ***(Added in April 2020)***;

(b) Where there is no regulatory regime which sets out external milestones or an objective framework to assess the development progress, market and clinical relevance of a product under the "Other Biotech Product" category, the Exchange will consider, for example ***(Added in April 2020)***:

(i) the number, selection process and diversity of the test sampling population, and availability of data from pre-clinical and clinical trials;

[4] 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 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.

(ii) time-frame and impediments to commercialisation;

(iii) whether the pre-clinical and clinical results have been published in medical/scientific journals. The Exchange will take into account the impact factor of the journals; and

(iv) where Competent Authorities have published relevant guidelines, their views and aspects of a comparable framework and/ or objective indicators of "Other Biotech Products".

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.

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 are allowed to participate in the IPO of a Biotech Company provided that the ~~issuer~~applicant complies with Main Board Listing Rules 8.08(1) and 18A.07 in relation to shares held by the public. For the avoidance of doubt, the Existing Shareholders Conditions in GL85-16 do not apply to Biotech Companies. For example:

(i) an existing shareholder holding less than 10% of shares in the Biotech Company may subscribe for shares in the IPO as either a cornerstone investor or as a placee. In the case of subscription as a placee, the applicant and its sponsor must confirm that no preference in allocation was given to the existing shareholder. In the case of subscription as a cornerstone investor, the applicant and its sponsor must confirm that no preference was given to the existing shareholder other than the preferential treatment of assured entitlement at the IPO price and the terms must be substantially the

same as other cornerstone investors.

(ii) an existing shareholder holding 10% or more of shares in the Biotech Company may subscribe for shares in the IPO as a cornerstone investor ***(Added in April 2020)***.~~.~~

5.3 An existing shareholder with a contractual anti-dilution right may exercise such right and subscribe for shares in the IPO in accordance with the existing requirements under paragraph 3.10 of GL43-12 ***(Added in April 2020)***~~.~~.

5.4 Where allocations will be made to core connected persons, the Biotech Company must apply for, and the Exchange will ordinarily grant, a related Rule 9.09 waiver, if applicable ***(Added in April 2020)***.~~.~~

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

7.1 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).

8. Clawback mechanism

8.1 Biotech Companies potentially carry additional risks to retail investors. Where Biotech Companies wish to propose any modification to the minimum public subscription requirement under Practice Note 18 of the Rules in an IPO, they must provide compelling reasons for such modification to the Exchange, which will be considered on a case-by-case basis ***(Added in April 2020)***.

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