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New HKEx Guidance for Biotech Companies Listing under Chapter 18A

The Hong Kong Stock Exchange (**HKEx**) issued new and updated guidance letters in April 2020 to assist pre-revenue Biotech companies applying to list under Chapter 18A of the Main Board Listing Rules (**Chapter 18A**). The latest guidance follows a review by HKEx of how Chapter 18A operates and comprises:

- Revised Guidance Letter HKEx-GL92-18 - Suitability for Listing of Biotech Companies[1] providing additional guidance on the suitability criteria for pre-revenue Biotech listing applicants and clarifying the circumstances in which a listing applicant's existing shareholders can subscribe in its IPO; and

- New Guidance Letter HKEx-GL107-20 - Disclosure in Listing Documents for Biotech Companies[2] which sets out disclosure guidance specific to pre-revenue biotech companies applying to list under Chapter 18A which supplements Guidance Letter HKEX-GL86-16's general disclosure guidance for all listing applicants.

The latest HKEx guidance addresses issues that Biotech companies have encountered in listing under Chapter 18A and provides greater clarity on the listing criteria and listing document disclosure requirements for pre-revenue Biotech companies applying to list under Chapter 18A.

HKEx's Updated Guidance on Biotech Listing Applicants' Suitability for Listing

HKEx has revised Guidance Letter HKEx-GL92-18 on the factors that it considers in determining whether a Biotech company is suitable for listing as required by Main Board Listing Rule 18A.03(1). Please refer to the blacklined version of HKEX-GL92-18[3] to view the latest amendments.

Suitability Criteria: R&D

Guidance Letter HKEx-GL92-18 sets out the criteria for a Biotech company to be considered suitable for listing which include that it must have been primarily engaged in R&D for the development of its Core Product(s) for at least 12 months prior to listing (Paragraph 3.2 of HKEx-GL92-18). The guidance letter updates set out the following expanded examples of what the HKEx will accept as meeting this requirement:

i) The following will demonstrate that a listing applicant has made progress in respect of R&D for an in-licensed or acquired Core Product since the in-licensing/acquisition: (a) showing that an in-licensed or acquired product proceeded from the preclinical to clinical stage or from one clinical

1 HKEx-GL92-18. Suitability for listing of biotech companies. Available at: https://www.hkex.com.hk/-/media/HKEX-Market/Listing/Rules-and-Guidance/Interpretation-and-Guidance-Contingency/Guidance-Letters/Guidance-Letters-for-New-Applicants/gl92_18.pdf

2 HKEx-GL107-20. Disclosure in listing documents for Biotech Companies. Available at: https://www.hkex.com.hk/-/media/HKEX-Market/Listing/Rules-and-Guidance/Interpretation-and-Guidance-Contingency/Guidance-Letters/Guidance-Letters-for-New-Applicants/gl107_20.pdf?la=en

3 Archived blacklined version of HKEx-GL92-18. Available at: https://www.hkex.com.hk/-/media/HKEX-Market/Listing/Rules-and-Guidance/Archive/Guidance-Letters/gl92_18.pdf?la=en

phase of the clinical trial to the next; or (b) an in-licensed or acquired product's receipt of approval for marketing from the relevant Competent Authority.

ii) If a Core Product has been commercialised in a particular market for a specific indication and the Biotech company plans to use part of the listing proceeds to expand the indications of the commercialised product or launch it in another market, the HKEx would expect additional R&D on the Core Product pertaining to the clinical trials required by the Competent Authority for a new indication or commercialisation in a new regulated market.

Suitability Criteria: Primary Reason for Listing

Another suitability criterion is that the primary reason for listing must be to raise funds for R&D to bring the company's Core Product(s) to commercialisation (Paragraph 3.2(d) of HKEx-GL92-18). The amended guidance letter provides specific guidance for Biotech companies that develop medical devices with short development cycles. The HKEx may take into account these companies' business plans and the development stage of the pipeline products to allow them to apply part of the listing proceeds to, for instance, establishing production facilities that will be used principally for manufacturing Core Products to bring them to commercialisation, and establisting sales, marketing and medical teams to commercialise the Core Products.

HKEx Suitability Criteria: Core Product Developed beyond the Concept Stage

Classification of "Other Biotech Products"

Further guidance has been added on how a Biotech listing applicant can demonstrate that it meets the suitability criterion that it has developed at least one Core Product beyond the concept stage which requires the Core Product to have reached the developmental milestones stipulated for the relevant type of product (Paragraph 3.2(a) of HKEx-GL92-18). The types of products covered in the guidance letter are pharmaceutical (small molecule drugs), biologics and medical devices (including diagnostics), and other biotech products falling outside these categories. The amendments to HKEx-GL92-18 clarify that the HKEx will classify Biotech products falling outside the main categories according to their classification by the relevant Competent Authority. This means that a Biotech Product which is regulated as a pharmaceutical, biologics or medical device cannot be re-categorised as "Other Biotech Product" because it cannot satisfy the requirements for the relevant category.

The revised guidance also provides that if there is no regulatory regime specifying external milestones or an objective framework for evaluating the development progress, market and clinical relevance of a product classified under the "Other Biotech Product" category, the HKEx will take into account various factors including:

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

ii) the time-frame and barriers to commercialisation;

iii) whether the preclinical and clinical results have been published in medical or scientific journals; and

iv) if Competent Authorities have published applicable guidelines, their opinions and aspects of a comparable framework and/or objective indicators of "Other Biotech Products".

These "Other Biotech Products" amendments are largely based on the now-withdrawn FAQ 035-2018 of the Emerging and Innovative Sectors FAQs.

In-licensed and Acquired Core Products

In relation to the developmental milestones stipulated for an in-licensed or acquired Core Product that is classified as pharmaceutical or biologic, the updated guidance letter provides that the Biotech company is expected to have finished at least one clinical trial regulated by the applicable Competent Authority on human subjects since the in-licensing or acquisition. If the listing applicant has not concluded any clinical trial on an in-licensed or acquired Core Product, the HKEx will assess why no clinical trial has been completed and whether the Biotech company has carried out substantive R&D work and processes (other than administrative processes) equivalent to the completion of one clinical trial on human subjects (New paragraphs 3.3(a)(iii) and (b)(iii) of the guidance letter).

Subscription of IPO Shares by Existing Shareholders

Given the expectation that the pre-listing shareholders of pre-revenue Biotech companies listing under Chapter 18A will continue to make capital contributions to enable the companies to bring their Core Products to commercialisation, the HKEx Listing Rules allow a Biotech listing applicant's existing shareholders to participate in its IPO, subject to it meeting the public float requirements of Listing Rules 8.08(1) and 18A.07.

HKEx-GL92-18 has been amended to clarify that the "existing shareholders conditions" restricting the circumstances in which a listing applicant's existing shareholders and their close associates can participate in an IPO (as set out in Guidance Letter HKEX-GL85-16 "Placing to connected clients, and existing shareholders or their close associates, under the Rules"[4]) do not apply to pre-revenue Biotech companies listing under Chapter 18A. This is also reflected in amendments to HKEX-GL85-16.

The revised guidance letter spells out that an existing shareholder holding less than 10% of a Biotech company's shares can subscribe for IPO shares either as a cornerstone investor or a placee. The listing applicant and the sponsor must confirm that no preference in allocation was given to the existing shareholder (other than the preferential treatment of assured entitlement at the IPO price in the case of cornerstone investor subscriptions).

An existing shareholder holding 10% or more of the Biotech listing applicant's shares can subscribe as a cornerstone investor only.

Existing shareholders that act as cornerstone investors must be subject to substantially the same terms as the other cornerstone investors. The amended guidance letter specifies that an existing shareholder with a contractual anti-dilution right may exercise that right and subscribe for shares in the IPO. Here, the existing anti-dilution rights requirements under paragraph 3.10 of Guidance Letter HKEX-GL43-12 "Guidance on Pre-IPO investments"[5] apply. These guidance provisions were previously set out in FAQ 038-2018 of the Emerging and Innovative Sectors FAQs.

Subscriptions by Core Connected Persons

HKEx-GL92-18 now provides that if shares are to be allocated to a Biotech listing applicant's core connected persons, the listing applicant must apply to the HKEx for a waiver from Listing Rule 9.09 which will normally be granted. Listing Rule 9.09 prohibits core connected persons from dealing in the securities for which listing is sought.

Clawback Mechanism

A clawback mechanism has been added which requires pre-revenue Biotech companies to present compelling reasons if they propose any amendment to the minimum public subscription requirement under Practice Note 18 of the Listing Rules. HKEx will consider requests for amendments case by case.

New Disclosure Guidance for Biotech Companies Listing on HKEx (HKEx-GL107-20)

New Guidance Letter HKEx-GL107-20 provides guidance on listing document disclosure which is specific to pre-revenue biotech companies applying to list under Chapter 18A. This supplements the general disclosure guidance for all listing applicants provided by Guidance Letter HKEX-GL86-16 Guide on Producing Simplified Listing Documents Relating to Equity Securities for New Applications.[6]

The overarching requirements for listing document disclosure apply to Chapter 18A listing applicants: namely that the information contained in a listing document must: (i) be accurate and complete in all material respects and not misleading or deceptive (HKEx Listing Rule 2.13(2)); and (ii) contain the particulars and information necessary for investors to make an informed assessment of the issuer (HKEx Listing Rule 11.07). The guidance on the disclosure required by Chapter 18A pre-revenue biotech listing applicants is summarised below.

Listing Document Summary Section

Guidance Letter HKEx-GL86-16 sets out the basic disclosure requirements for companies applying to list on the Hong

4 HKEx-GL85-16. Placing to connected clients, and existing shareholders or their close associates under the Listing Rules. Available at: https://www.hkex.com.hk/-/media/HKEX-Market/Listing/Rules-and-Guidance/Interpretation-and-Guidance-Contingency/Guidance-Letters/Guidance-Letters-for-New-Applicants/gl85-16.pdf?la=en

5 HKEx-GL43-12. Guidance on Pre-IPO investments. Available at: https://www.hkex.com.hk/-/media/HKEX-Market/Listing/Rules-and-Guidance/Interpretation-and-Guidance-Contingency/Guidance-Letters/Guidance-Letters-for-New-Applicants/gl43-12.pdf?la=en

6 HKEX-GL86-16. Guide on Producing Simplified Listing Documents Relating to Equity Securities for New Applications. Avaliable at: https://en-rules.hkex.com.hk/sites/default/files/net_file_store/new_rulebooks/g/l/gl8616.pdf

Kong Stock Exchange. New Guidance Letter HKEx-GL107-20 requires Biotech listing applicants to make additional disclosure in the Summary section including a scientific description of the biotech technology and key clinical data for the listing applicant's Core Products. Given the extent of retail investor interest in Biotech listings, Guidance Letter HKEx-GL107-20 sets out the following guidance for the "Summary" section:

i) Simple and plain language should be used when possible (provided that this does not compromise scientific accuracy);

ii) Full terms and plain language explanations should be included when a key abbreviation is first used in the "Summary" section;

iii) Meaningful headings and sub-headings should be used to highlight content;

iv) Cross-references should be made to the "Business" section for highly technical information or detailed scientific descriptions;

v) A timetable for the development of Core Products should be prepared in a fair and balanced way which does not present favourable possibilities as certain or more probable than is likely to be the case; and

vi) A risk factor should be included that investors may lose all their investments in the Biotech company because research and development (**R&D**) failure may materially and adversely effect the company's ongoing prospects.

Competitive Landscape and Addressable Market Disclosure

HKEx requires disclosure of the competitive landscape of the listing applicant's Core Products and other key pipeline products proposed to be commercialised in targeted markets. Disclosure should cover: (i) competitors' current pipeline of products that target the same indication, with their development phases; (ii) the name, price and reimbursement coverage of such products (where applicable); and (iii) the expiration dates of key patents of competitor products (where available).

There should be disclosure of material information on the applicable addressable market of Core Products and other key pipeline products, as opposed to the overall market. Biotech Companies' products should be compared with products that are in direct competition covering key areas including technologies, indications and target market.

Communication with Competent Authorities

In satisfying the listing requirement to disclose a summary of material communications with the relevant Competent Authority in relation to Core Products (Listing Rule 18A.04(2)(c)), new Guidance Letter HKEx-GL107-20 provides that there should be disclosure of all meaningful data (including whether material concerns or objections have been raised by China's National Medical Products Administration in relation to completed or ongoing clinical trials) or a negative statement where there is no communication with the relevant Competent Authority.

Commercialised Core Products

If a Core Product has been commercialised in a market for specific indication and the Biotech company plans to utilise part of the listing proceeds for expanding the indications or launching the product in another market, there should be disclosure of a breakdown of the funds for R&D (e.g. resources to support additional studies) and their significance in advancing the Core Product.

Core Products and Advanced Pipeline Candidates Classified and Regulated as Orphan Medicines and/or Innovative Therapies

In respect of orphan medicines and/or innovative therapies, there should be disclosure of the basis for the drug candidate to qualify for a specific regulatory pathway, any exemptions granted for particular regulatory processes, and the advantages of being approved under that pathway.

The commercialisation plan and/or market strategy for a drug product's entry into a primary or other market should be set out. This should include a timeline of the regulatory milestones before submission of the new drug application, as well as the major differences between markets.

The caliber and experience of research institutions participating in a collaboration should be disclosed. The listing document should also identify material terms and conditions of the collaboration and who will own the intellectual property, patent and sub-licensing rights (if any).

Pipeline Products

Biotech companies must identify the origins and the jurisdictional rights relating to Biotech products. The origin of a Biotech Company's product may be through internal development or in-licensing.

The listing document should highlight pipeline products that are strategically or commercially essential to the Biotech company whose development will be prioritised, or to which a significant part of the listing proceeds will be applied.

Material information on studies for each pipeline product should be disclosed in a balanced manner, for example pre-clinical/ clinical data regardless of whether the results are favourable or not, and its development progress and plan. This information should be summarised in the pipeline table.

Biotech companies should consider excluding from listing documents information on products which are at a very early pre-clinical stage, for which there is no meaningful pre-clinical research data or the data is scientifically sensitive.

Guidance Letter HKEx-GL107-20 reminds sponsors to carry out adequate due diligence to ensure that the disclosure of biotech products is accurate and that risk factors relating to their inherent uncertainties are disclosed.

Valuation

There should be disclosure of valuation of each round of pre-IPO investment, and an explanation of any material fluctuations in valuation with the immediate previous round of pre-IPO financing with reference to key product developments, business milestones and competitive advantages over competitors.

Sophisticated Investors

Material information on Sophisticated Investors should be disclosed, such as their background and track record in the relevant biotech industry.

Net Liabilities

Where a Biotech company has net liabilities during its track record period due to significant fair value change of convertible financial instruments and they will be fully converted upon listing so that there will be a net assets position, disclosure should be made in the "Summary" and "Risk Factors" sections.

Burn Rate

A Biotech company should disclose in the "Summary" and other relevant sections a reasonable time period, with reasons, during which it can maintain its viability with its existing cash balance (both with and without the IPO proceeds). The company should also disclose when it anticipates conducting its next round of financing based on its burn rate.

Contractual Arrangements

Biotech companies that adopt contractual arrangements (i.e. VIE structures) should refer to Listing Decision HKEX-LD43-3.[7] According to the listing decision, contractual arrangements should only be used to the extent necessary to address any limits on foreign ownership. This also applies to Biotech companies.

Revisions to HKEx FAQs on Emerging and Innovative Sector Companies - Principal Investigator Disclosure

HKEx also updated its Frequently Asked Questions on Listing Regime for Companies from Emerging and Innovative Sectors[8] in April 2020. Revised FAQ 039-2019 now provides that where a principal investigator who is in charge of or supervises a Biotech company's clinical trial has additional roles in the Biotech Company (e.g. acting as a member of a scientific advisory panel) for which they receive compensation, the listing document should disclose the investigator's specific functions in the company, the terms of any compensation and whether the compensation paid to the principal investigator could impair the integrity of the company's clinical trial.

7 HKEX-LD43-3. Listing Decision on whether Contractual Arrangments would render a company unsuitable for listing. Avaliable at: https://en-rules.hkex.com.hk/sites/default/files/net_file_store/new_rulebooks/l/d/LD43-3.pdf

8 Frequently asked questions on listing regime for companies from emerging and innovative sectors. Available at: https://en-rules.hkex.com.hk/sites/default/files/net_file_store/new_rulebooks/f/a/FAQ_030_to_044.pdf

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