May 26 2020

NEW GUIDANCE FOR BIOTECH COMPANIES HKEX-GL92-18

HKEX 香港交易所

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AGENDA

1. Listing Rules/Guidance Materials of Biotech Chapter
2. Rationale behind updated and new Guidance Materials
3. Key updates in GL92-18

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Listing Rules/Guidance Materials of Biotech Chapter

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.

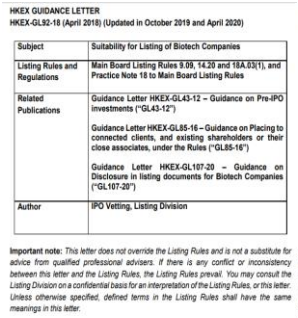
DEFINITIONS AND INTERPRETATION

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.

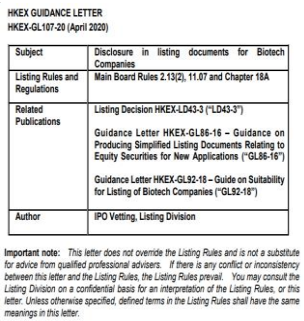
CHAPTER 18A



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")
Author	IPO Vetting, Listing Division

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 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.*



HKEX GUIDANCE LETTER
HKEX-GL107-20 (April 2020)

Subject	Disclosure in listing documents for Biotech Companies
Listing Rules and Regulations	Main Board Rules 2.13(2), 11.07 and Chapter 18A
Related Publications	Listing Decision HKEX-LD43-3 ("LD43-3") Guidance Letter HKEX-GL86-16 – Guidance on Producing Simplified Listing Documents Relating to Equity Securities for New Applications ("GL86-16") Guidance Letter HKEX-GL92-18 – Guide on Suitability for Listing of Biotech Companies ("GL92-18")
Author	IPO Vetting, Listing Division

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 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.*

- Chapter 18A
  - conditions for listing
  - contents of listing documents
  - continuing obligations
- Guidance Letter (GL92-18)
  - supplements suitability for listing
- Guidance Letter (GL107-20)
  - supplements disclosure in listing documents

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1 Listing Rules/Guidance Materials of Biotech Chapter

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3 Key updates in GL92-18

Rationale behind updated and new Guidance Materials

- Address the evolving complexity of the biotech industry
- Common issues encountered by Biotech Companies since the introduction of Chapter 18A
- Revised GL92-18 and introduced GL107-20
  - provide more clarity on requirements for listing and the required disclosure
  - facilitate Biotech Companies and market practitioners in the listing process and preparation of listing documents

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1 Listing Rules/Guidance Materials of Biotech Chapter

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Update #1 – R&D progress of a Core Product (paragraph 3.2(c)(i))

- In-licensed or acquired core Product

  - Biotech Company must demonstrate R&D progress such as:

    - progressed from pre-clinical stage to clinical stage

    - progressed from one to next clinical phase

    - obtained regulatory approval

Update #2 – R&D of commercialised Core Product (paragraph 3.2(c)(ii))

- Commercialised Core Product

  - Biotech Company applies a portion of listing proceeds to:

    - expand new indications

    - launch in new regulated market

Update #3 – Primary reason for listing (paragraph 3.2(d))

- For medical devices issuers with short development cycle:
  - depending on the business plan and development stage of pipeline products, may allocate a portion of the listing proceeds to:
    - set up manufacturing production facilities
    - establish sales, marketing and medical teams

Update #4 – Core Product beyond concept stage (paragraph 3.3(a) and (b))

- For a pharmaceutical or a biologic, Biotech Company:
  - must complete at least one regulated clinical trial in human subjects; or
  - explains why no clinical trial has been completed and whether substantive R&D work and processes equivalent to the completion of one clinical trial have been performed

Update #5 – Other Biotech Products (paragraph 3.4)

- Biotech Product is categorised under GL92-18 as it is categorised by the Competent Authority
- No re-classification of a Biotech Product as “Other Biotech Product” because it is unable to fulfil the requirements under paragraph 3.3
- Where there is no regulatory regime, a Biotech Product can be classified as “Other Biotech Product” after considering non-exhaustive factors such as:

  - number, selection process and diversity of test sampling population
  - time frame and impediments to commercialisation
  - impact factor of journals if pre-clinical and clinical results have been published
  - comparable framework and/or objective indicators under guidelines published by Competent Authorities

Update #6 – Subscription by existing shareholder (paragraph 5.2)

- Existing Shareholder Conditions in GL85-16 do not apply to Biotech Company
- Biotech Companies' existing shareholders are allowed to participate in IPO. For example, an existing shareholder holding:
  - <10% of a Biotech Company's shares may subscribe for shares as a cornerstone investor or as a placee
  - ≥10% of a Biotech Company's shares may subscribe for shares as a cornerstone investor
  - an existing shareholder may exercise its contractual anti-dilution right and subscribe for shares
- Until Rule changes, need to apply for a waiver under Rule 9.09

Update #7 – Clawback mechanism (paragraph 8.1)

- Compelling reasons must be provided for modifications or waiver to the minimum public subscription requirement under Practice Note 18 of the Rules

- The Exchange will consider all applications on a case-by-case basis

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DISCLOSURE GUIDANCE FOR BIOTECH COMPANIES HKEX-GL107-20

HKEX 香港交易所

Dr. Wei Zhang
Listing Division

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1. Purpose of GL107-20
2. Major guidance under GL107-20

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1 Purpose of GL107-20

2 Major guidance under GL107-20

GL107-20 – Recommended disclosure requirements

- GL86-16 “Guide on Producing Simplified Listing Documents Relating to Equity Securities for New Applications” still applies
- GL107-20 supplements GL86-16 and is intended to assist Biotech Companies in drafting their listing documents
- Listing document that does not follow GL107-20 may be considered not substantially complete

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1 Purpose of GL107-20

2 Major guidance under GL107-20

Summary section

- Plain language, full terms of key abbreviations when they first appear
- Cross-reference to Business section for highly technical content or detailed mechanism of action and full set of clinical results
- Provide fair and balanced timetable of Core Products' development and avoid presenting favourable possibilities as certain or as more probable
- Risk factor that potential investors may lose all their investments

Competitive landscape

- Core Products and other key pipeline products to be commercialised in targeted markets
  - competitors' current pipeline products targeting the same indication and their development stages
  - name, price and reimbursement coverage of available products
  - expiration dates of competing products' key patents, etc.

- Material information on the addressable market of Core Products and other key pipeline products rather than the overall market

- Comparison between Biotech Companies' products and direct competing products in major areas such as technologies, indications, targeting market, etc.

Communication with Competent Authorities

- Competent Authorities include:
  - National Medical Products Administration (NMPA)
  - US Food and Drug Administration (FDA)
  - European Medicines Agency (EMA)
  - other national or supranational authorities on a case-by-case basis
- Rule 18A.04(2)(c) *vs.* NMPA's umbrella approval
  - Rule 18A.04(2)(c) requires disclosure of a summary of material communication with relevant Competent Authorities on Core Products
  - for NMPA's umbrella approval: disclose whether NMPA has raised material concerns or objections towards clinical trials or a negative statement
  - for FDA and EMA: disclose all meaningful communication

Commercialised Core Product

- Disclosure for a commercialised Core Product in a given market for specified indication and intends to apply a portion of the listing proceeds to expand (a) the indications; or (b) launch it in another market:
  - a breakdown of the funds to support R&D, e.g. resources required to support further studies
  - importance in advancing the Core Product

Core Product and advanced pipeline candidates as orphan medicine and/or innovative therapy

- Drug pathway classification
  - any special regulatory pathway

- Regulatory strategy
  - any special commercialisation plan and/or market strategy to enter a primary market and other markets

- Collaboration with third party
  - experience of the third party and material terms of the collaboration

Pipeline products

- Specify the origins
  - internally developed or in-licensed?
  - jurisdiction rights (global? PRC? etc.)
- Highlight pipeline products
  - strategically and commercially critical to Biotech Company and Biotech Company will prioritise its development
  - a significant portion of proceeds will be applied
- Balanced disclosure
  - both favourable and unfavourable pre-clinical/clinical data
- Early pipeline products without any meaningful data should not be included
- Sponsors are responsible for accuracy of disclosure of pipeline products

Valuation and Sophisticated Investors

- Valuation
  - disclose valuation of each round of pre-IPO investments
  - explain any material fluctuations in each round of pre-IPO financing with reference to:
    - key development of the products
    - business milestones
    - competitive advantage over the peers

- Sophisticated Investors
  - disclose material information (e.g. fund's background and track record)

Net liabilities and burn rate

- Net liabilities (in Summary and Risk Factor sections)
  - turning into a net assets position as a result of full conversion of convertible financial instruments upon listing

- Burn rate (in Summary and other relevant sections)
  - a reasonable period of time that a Biotech Company can maintain its viability

  - expected time for next round of financing

Contractual arrangements

- Listing Decision LD43-3 on contractual arrangements applies to Biotech Companies
- Contractual arrangements should only be adopted to meet foreign ownership restrictions

Thank You