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")**
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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 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 Chapter 18A of the Main Board Rules ("**Chapter 18A**") became effective on 30 April 2018. The Exchange has recently reviewed the operation of Chapter 18A and based on the comments from the Listing Committee, SFC, market practitioners and members from the biotech advisory panel has identified certain disclosure in listing documents which can be enhanced.

1.2 The Exchange has published guidance on disclosure in listing documents applicable to all companies including Biotech Companies listing under Chapter 18A. This letter supplements such guidance and is intended to assist Biotech Companies suitable for listing under Chapter 18A in drafting their listing documents.

1.3 A listing document that does not follow this guidance may be considered not substantially complete as required under the Listing Rules.

2. Relevant Listing Rules

2.1 Main Board Rule 2.13(2) provides that the information contained in the listing document must be accurate and complete in all material respects and not be misleading or deceptive.

2.2 Main Board Rule 11.07 sets out an overriding general principle of disclosure in a listing document.

2.3 Chapter 18A sets out the requirements for Biotech Companies.

3. Guidance

3.1 The Exchange suggests that the following disclosure be made in the listing documents which fall under Chapter 18A, where applicable.

Key areas	Disclosure recommendations
Summary Section	Reference should be made to GL86-16[1] which sets out basic requirement for all applicants. Given the nature of the biotech industry, the disclosure in the Summary section will include scientific description of the biotech technology, key clinical data of Core Products, etc. As Biotech Companies have attracted significant retail investor interest and they may not possess deep knowledge of biotechnology and medical science, Biotech Companies should take the following into consideration when drafting the Summary section: ● use simple/plain language, when possible, on the basis that scientific accuracy is not compromised ● provide full terms and explain them using plain language when a key abbreviation first appears in the Summary section ● use meaningful headings and sub-headings to highlight the content ● cross-reference to the Business section for highly technical content or detailed description of sciences, such as mechanism of action and full clinical data ● disclose development timetable of Core Products in a fair and balanced manner and avoid presenting favourable possibilities as certain or as more probable than is likely to be the case ● disclose a risk factor that potential investors may lose all their investments in the Biotech Company as failure of R&D may have a material adverse impact on the its ongoing prospect
Competitive landscape and addressable market	● disclose competitive landscape of Biotech Company's Core Products and other key pipeline products to be commercialised in targeted markets, including (1) competitors' current pipeline products

[1] Guide on Producing Simplified Listing Documents Relating to Equity Securities for New Applications.

Key areas	Disclosure recommendations
	targeting the same indication and their development stages; (2) the name, price and reimbursement coverage of such available products, if applicable; and (3) expiration dates of competing products' key patents, etc., as the case may be and if available ● disclose material information on the relevant addressable market of Core Products and other key pipeline products rather than the overall market (and the potential addressable market size should be consistent with the potential competitive landscape presented by the Biotech Companies) ● a 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 have adopted different procedures in interphase clinical trial approval. For example, China's National Medical Products Administration ("**NMPA**"), a Competent Authority, has adopted a one-time umbrella approval procedure since 2015 for any new drug's clinical trial application (i.e. including Phase I to Phase III) and may not grant phase-by-phase approval or issue further confirmation. In order to meet Rule 18A.04(2)(c) which requires Biotech Companies to disclose a summary of material communication with relevant Competent Authorities in relation to their Core Products: ● Biotech Companies should disclose all meaningful data including whether the NMPA has raised material concerns or objections towards the completed or ongoing clinical trials[2] or a negative statement if there is no communication between the Biotech Company and the relevant Competent Authority
Commercialised Core Products	In the case of a Core Product which has been commercialised in a given market for specified indication and the Biotech Company intends to apply a portion of the

[2] For the avoidance of doubt, where clinical trials are conducted and regulated by other Competent Authorities, their communication with Biotech Companies on the Core Products are required to be disclosed under Rule 18A.04(2)(c).

Key areas	Disclosure recommendations
	listing proceeds to expand the indications of the commercialised Biotech Product or launch it in another market: ● disclose (a) a breakdown of the funds to support R&D. Non-exhaustive examples include resources required to support further studies; and (b) their importance in advancing the Core Product
Core Products and advanced pipeline candidates classified and regulated as orphan medicines and/or* innovative *therapies	*Drug pathway classification* ● disclose the basis for drug candidates to qualify in a particular regulatory pathway, the exemptions granted by the relevant Competent Authorities in certain regulatory processes and the advantages therein for drug products admitted, reviewed and potentially approved under such designation *Regulatory strategy* ● disclose the commercialisation plan and/or market strategy to be taken for a particular drug product to enter a primary market and other markets, including timeline of the next regulatory milestones leading up to the filing of new drug applications, and key differences between the primary market and other markets, if applicable *Collaboration* ● define the calibre and experience of participating research institutions in a collaboration, material terms and conditions of the collaboration and who will own the intellectual property rights, patent and sub-licensing rights, if applicable
Pipeline products	● specify the origins (i.e. in-licensing or internally-developed) and the jurisdiction rights pertaining to the Biotech Products ● highlight pipeline product that is strategically or commercially critical to the Biotech Company and the Biotech Company will prioritise its development; or that the Biotech Company intends to apply a significant portion of listing proceeds to it even if it has not been developed beyond the concept stage ● ensure a balanced disclosure of material information

Key areas	Disclosure recommendations
	on relevant studies (e.g. preclinical/clinical data, irrespective of whether there are favourable or unfavourable results, and development progress, how long it has been developed by the Biotech Companies and future development plan) for each pipeline product, and summarise such information in the pipeline table ● for products which are at very early preclinical stage and the Biotech Company does not have any meaningful preclinical research data, or the data is deemed scientifically sensitive, the Biotech Company should consider excluding them from the listing document ● sponsors are reminded to conduct sufficient due diligence to ensure the accuracy of the disclosure on these products, and disclose associated risk factors on the inherent uncertainties on such pipeline products
Valuation	● disclose valuation of each round of pre-IPO investments and explain material fluctuations in valuation with the immediate previous round of pre-IPO financing with reference to key development of the products, business milestones, and competitive advantage over its peers
Sophisticated Investors	● disclose material information on Sophisticated Investors (e.g. fund's background and track record in the relevant biotech or healthcare industries)
Net liabilities[3]	● disclose in the Summary and Risk Factors sections if the Biotech Company incurred net liabilities during the Track Record Period as a result of significant fair value change of convertible financial instruments and that they will be fully converted upon listing, therefore turning into a net assets position, if applicable
Burn rate	● disclose in the Summary and other relevant sections: − a reasonable period of time, with basis, that a Biotech Company can maintain its viability with

[3] This is applicable to all listing applicants (see GL86-16).

Key areas	Disclosure recommendations
	existing cash balance with and without the IPO proceeds − when the Biotech Company expects to raise its next round of financing based on its burn rate
Contractual arrangements	● LD43-3 on contractual arrangements sets out that contractual arrangements should only be adopted to meet foreign ownership restrictions and this position also applies to Biotech Companies. Biotech Companies should therefore refer to LD43-3 if they adopt contractual arrangements

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