**HKEX GUIDANCE LETTER**

**HKEX-GL107-20 (April 2020) (Updated in February 2021)**

**[Streamlined and incorporated into the Guide for New Listing Applicants in January 2024]**

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| **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")**<br><br>**Guidance Letter HKEX-GL86-16 – Guidance on Producing Simplified Listing Documents Relating to Equity Securities for New Applications ("GL86-16")**<br><br>**Guidance Letter HKEX-GL92-18 – Guidance on Suitability for Listing of Biotech Companies ("GL92-18")**<br><br>**Guidance Letter HKEX-GL98-18 – Guidance on disclosure in listing documents - listing applicants' names; statistics and data quoted; listing document covers; non-disclosure of confidential information; and material changes after trading record period ("GL98-18")** |
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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 reviewed the operation of Chapter 18A, and identified certain areas in listing documents of Biotech Companies where disclosure can be enhanced.

1.2 This letter provides guidance aiming to improve drafting of listing documents of Biotech Companies. It supplements guidance which the Exchange has published relating to disclosure in listing documents applicable to all listing applicants. ***(Updated in February 2021)***

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

## 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

*Overall drafting*

*Fair, balanced and accurate disclosure*

3.1 Given the business nature of Biotech Companies, there is uncertainty over whether their R&D will lead to commercialisation of their product candidates eventually. As such, it is especially important that Biotech Companies should present fair, balanced and accurate information to potential investors, particularly due to the fact that listings of Biotech Companies in Hong Kong have attracted significant retail participation to date. To facilitate investors in assessing the scientific strengths and developments of Biotech Companies (compared to their peers), applicants are also expected to provide clear, precise disclosure on, among other things, their business models and products without compromising the scientific accuracy. ***(Added in February 2021)***

3.2 Set out below are non-exhaustive examples where the disclosure was considered misleading and failed to present a fair and balanced position of the applicants and their businesses:

(a) an applicant described itself as "global" where its products only target a particular jurisdiction, or it has only limited operation overseas while the majority of its operation (e.g. R&D) is located in one particular jurisdiction;
(b) an applicant which had yet to commercialise any of its product candidates described itself as *"a company with robust execution capabilities"* and/or *"having a proven track record"*; and
(c) an applicant did not state specifically at which stage its clinical trials were and used vague and unsubstantiated language such as "*late-stage and near late-stage clinical trials*", *"near commercialisation"*, and "*a great pipeline*" (when the majority of the products are at an early stage). ***(Added in February 2021)***

*Avoid marketing language, emotional expressions and unsubstantiated descriptions*

3.3 As an overriding principle, all applicants should avoid marketing language in the listing documents according to GL86-16 [1], and emotional expressions and

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

unsubstantiated descriptions should not be used. Non-exhaustive guidance include:

(a) a letter from chairman/management team which contains visionary and aspirational language and/or unsubstantiated projections should be avoided;
(b) overly emotional language or aggrandised marketing statement (e.g. "*the goal is to give life a second chance*") should be avoided; and
(c) the use of descriptions such as *"novel"*, *"top-notch"*, *"a leading company"*, *"blockbuster potentials"*, *"state-of-the-art technologies"*, and *"first-in-class/best-in-class products"* for their products or the use of descriptions such as *"completed a number of landmark investments"* and *"investing in high-quality middle-market companies"* for the background of pre-IPO investors should be specific and substantiated with basis or evidence. ***(Added in February 2021)***

*Use of diagrams and flowcharts for illustration purposes*

3.4 In view of the complexity and technicality involved in Biotech Companies' businesses, applicants are encouraged to use diagrams or flowcharts to explain their business models, and Core Products and key non-Core Products (e.g. mechanisms of action ("**MOA**")).

*Risk factors*

3.5 To fully apprise the investors of the risks associated with investing in Biotech Companies, applicants are urged to (a) arrange risk factors in the order of significance, disclose upfront the risk factors that are specific and critical to Biotech Companies generally and the applicants specifically (e.g. rights to develop and commercialise in-licensed products are subject to terms and conditions of the licensing agreements (including termination events), competitive landscape of specific relevant product, the risks on infringement and expiry of intellectual property ("**IP**") rights, potential investors may lose all their investments in case of failure of R&D or regulatory approval not forthcoming); (b) include a summary of the key risk factors in the Summary section; and (c) disclose the details of major adverse events, their actual and potential impact and the applicant's mitigating measures, where applicable (e.g. interruptions on clinical trials as a result of COVID-19, legal proceedings involving rights of the applicant's key products). ***(Added in February 2021)***

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

| Key areas | Disclosure recommendations |
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| ***Summary Section*** | Reference should be made to GL86-16 and GL98-18[2] which set out basic requirements for all applicants. As Biotech |

[2] Guidance on disclosure in listing documents - listing applicants' names; statistics and data quoted; listing document covers; non-disclosure of confidential information; and material changes after trading record period.

| Key areas | Disclosure recommendations |
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| ***(Updated in February 2021)*** | Companies have attracted significant retail investor interest and they may not possess deep knowledge of biotechnology and medical science, applicants should take the following into consideration when drafting the Summary section (including the scientific description of the applicant's R&D):<br>● use simple/plain language to the extent that scientific accuracy is not compromised<br>● provide full terms, explain them using plain language when a key abbreviation first appears in the Summary section, and cross-refer to the Business section for highly technical content or detailed description of sciences, such as MOA and full clinical data<br>● use meaningful headings and sub-headings to highlight the content<br>● disclose a clear and accurate summary of:<br>− the business model (see "Business model" subsection below) and where applicable, state clearly the division of responsibilities between the applicant and external parties such as collaborative partners, contract research organisation (CRO), contract manufacturing organisation (CMO) or other players<br>− Core Products and other key non-Core Products (including indication, prevalence/ incidence rates) (see "Products" subsection below)<br>− competitive landscape of Core Products and other key non-Core Products (see "Industry Overview" subsection below)<br>− key risks of the applicant and its products<br>● disclose development timetable of the 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<br>● highlight any expected material increase in costs or expenses (such as R&D expenses and marketing expenses in connection with its biotech products) during the period covered by the working capital forecast |
| ***Business*** | ● disclose clearly the business model(s) of the applicant in |

| Key areas | Disclosure recommendations |
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| ***model (Added in February 2021)*** | the Summary and Business sections. Business models adopted by Biotech Companies may include one of the following, or a combination of them and we expect applicants to disclose key aspects of their models (including a fair and balanced disclosure on the level of R&D undertaken and to be undertaken, which should correspond to the business model and the market potential, e.g. high market potential yet prone to more challenges and competition and higher uncertainty):<br>− in-licensing model<br>− self-developed model<br>● *<u>In-licensing arrangements</u>*<br>− the stage of development of its in-licensed products and the post-licensing R&D activities performed and to be performed by the applicant for such products (including actual and anticipated expenses and funding, research expertise required) and the product's latest development status by the licensor, if relevant (including without limitation any adverse information about the scientific validity or safety of the product)<br>− the material terms of relevant arrangements (e.g. licensing of specific patents and territories, milestone payments and their triggering events, termination events, key respective rights and obligations (including royalties and IP rights) of the applicant and the licensors, future related IP and residual IP rights arrangement, etc.) and whether any licensing payments will be paid out of listing proceeds<br>− the background and independence of the counter-parties to the in-licensing arrangements (including without limitation their operational scale)<br>− the clinical trial results and rights that belong to the applicant, and not to mix up with those attributable to the licensors / collaborative partners<br>● *<u>Out-licensing arrangements</u>*<br>− the major terms of the collaboration agreement, including the rights the applicant retains in relation to |

| Key areas | Disclosure recommendations |
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| | the out-licensed products, any material restriction on the applicant's right to R&D and commercialise such products, upfront, milestone and royalty payments and triggering points etc., which are similar to our recommendations on in-licensing arrangements |
| ***Products (Updated in February 2021)*** | ● specify the origins (i.e. in-licensing or internally-developed) and the jurisdiction rights pertaining to the Core Products and key non-Core Products<br>● ensure clear and accurate description of the products and their respective market opportunities in the Summary and other relevant sections, including indications of the products, target patient population (e.g. first-line/second-line treatment, etc.) and if applicable, prevalence and incidence rates of the disease in the corresponding jurisdiction where the applicant is conducting the clinical trials and plans to launch its products (e.g. available information on genetic or ethnic subgroups if the applicant's product is specific to a mutation), available treatment options, and current cost of treatment of the comparable product in the target market and other markets<br>● ensure a balanced disclosure of material information on relevant studies (e.g. relevant and up-to-date preclinical/clinical data, and development progress and future development plan) for each Core Product and key non-Core Product, and summarise such information in the pipeline table<br>● highlight the strategies implemented/to be implemented by the applicant in relation to:<br>− R&D, for example (1) self-developed innovative products based on novel or differentiated MOA where significant amount of R&D by the applicant is required; (2) self-developed products based on well-established MOA, including "me-too" or "me-better" products, where less R&D by the applicant may be required; and (3) in-licensed products where limited R&D may be required<br>− commercialisation, including timeline of the next |

| Key areas | Disclosure recommendations |
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| | regulatory milestones leading up to the filing of new drug applications or device registrations, and key differences between the primary market and other markets, if applicable<br>● define the calibre and experience of participating research institutions and their access to human subjects for clinical trials, if any, and disclose the material terms and conditions of the collaboration and who will own the IP rights, patent and sub-licensing rights, if applicable (see "Business model – In-licensing arrangements" subsection above)<br>● for products which the applicant has recorded sales during and/or after the track record period, the applicant should disclose information on such sales, including the information on the products sold, the background of the customers and the distribution channels used<br>● if applicable, highlight the non-Core Product that is strategically or commercially critical to the applicant, or for which the applicant intends to apply a significant portion of listing proceeds. Disclosure on such non-Core Products should be comparable to those on Core Products covering, for example, MOA, clinical data and competitive landscape<br>● for products which are at very early preclinical stage and the applicant does not have any meaningful preclinical research data, or the data is deemed scientifically sensitive, the applicant should consider excluding them from the listing document<br>● for products classified and regulated as orphan medicines and/or innovative therapies, the applicant should disclose (1) the basis for drug candidates to qualify in a particular regulatory pathway; (2) the exemptions granted during the regulatory process (if any) by the relevant Competent Authorities; and (3) the advantages for drug products admitted, reviewed and potentially approved under such designation<br>● for a Core Product which has been commercialised in a given market for specified indication and the applicant |

| Key areas | Disclosure recommendations |
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| | intends to apply a portion of the listing proceeds for further developing that product such as expanding the indications of the commercialised Core Product, launching it in another regulated market, or conducting further clinical trials required by the Competent Authority, the applicant should disclose:<br>(1) an overview of the strategies on the Core Product, including therapeutic and regional priorities<br>(2) the objective of further studies in advancing the Core Product, with a breakdown of the funds to support such further R&D and other development activities. Non-exhaustive examples include resources required to support further post-approval R&D required by a Competent Authority or further R&D with concrete plans for new indication/market |
| ***R&D team (Updated in February 2021)*** | ● disclose the size, experience, qualifications and areas of specialisation of the R&D team, and how long they have been working on similar products |
| ***Industry Overview (Updated in February 2021)*** | ● applicants and their sponsors are reminded to ensure the accuracy of industry data and statistics. Sources of data relied on by industry consultants (e.g. interview with experts) should be clearly disclosed. For example, if official data on certain target markets is not available, summaries of the bases and assumptions used by the industry consultants in deriving the industry data should be clearly disclosed. Sponsors are reminded that they need to check the reasonableness of such assumptions and bases<br>*<u>Competitive landscape and addressable market</u>*<br>● clearly define addressable markets of the Core Products and key non-Core Products (e.g. products that are only restricted to limited pool of patients for third-line treatment) rather than only the overall market and disclose material information of such markets (e.g. size, value and growth rates)<br>● disclose competitive landscape of the Core Products' and key non-Core Products' respective therapeutic areas and, to the extent applicable, include the following |

| Key areas | Disclosure recommendations |
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| | information of the competing or potentially competing commercialised or pipeline products: (1) the name, line of treatment, price (including similar products launched in other jurisdictions and factors that may affect pricing in the target market) and reimbursement coverage; (2) expiration dates of key IP rights; (3) technologies; and (4) addressable markets<br>● statements that the applicant's products are likely to be more competitive or better[3] should be substantiated |
| ***IP (Added in February 2021)*** | ● include in the Summary section the material IPs of the products, disclose the tenure and material payment obligations associated with such IP rights and residual IP rights, and whether such rights are in-licensed or self-owned<br>● clearly disclose (1) the part of the Core Product or key non-Core Product to which the material IPs are attributing or protecting (for example whether key technology or product packing); and (2) the extent and form to which such IPs are protected (e.g. whether patent is in the process of application, or patent has already been registered)<br>● highlight any risk of IP infringements in the Summary and Risk Factors sections, and disclose a positive statement by the directors (supported by the sponsor's due diligence) as to whether the applicant had any instances of infringement of third parties' IP rights and, if so, the relevant details and potential impact on the applicant's operation |
| ***Communication with Competent Authorities (Updated in February 2021)*** | 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 |

[3] For example, a product being first-in-class may simply mean that it has a new MOA, but does not necessarily mean that the product is better.

| Key areas | Disclosure recommendations |
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| | 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:<br>● an applicant should disclose all material interactions with the Competent Authorities and the results of such interactions, whether the NMPA has raised material concerns or objections towards the completed or ongoing clinical trials[4] or it has "no objection" to the applicant's commencement of phase II (or later) clinical trials (if any), or a negative statement if there is no communication between the applicant and the relevant Competent Authority |
| ***Valuation (Updated in February 2021)*** | ● disclose valuation of each round of pre-IPO investments in a table, and reasons for material fluctuations in valuation (1) as compared to the immediate previous round of pre-IPO financing; and (2) between the proposed IPO valuation and the valuation in the latest round of pre-IPO financing, such as key development of the products and business milestones |
| ***Sophisticated Investors (Updated in February 2021)*** | ● disclose material information on Sophisticated Investors (e.g. fund's background and track record in the relevant biotech or healthcare industries) (see GL92-18[5] for the indicative benchmark of a "meaningful investment" by Sophisticated Investors) |
| ***Net liabilities[6]*** | ● disclose in the Summary and Risk Factors sections if the applicant 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: |

[4] 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).

[5] Guidance on Suitability for Listing of Biotech Companies.

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

| Key areas | Disclosure recommendations |
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| ***(Updated in February 2021)*** | − a reasonable period of time, with basis, that the applicant can maintain its viability with existing cash balance with the IPO proceeds<br>− when the applicant expects to raise its next round of financing based on its burn rate<br>− an applicant should have reasonable assumptions in relation to the burn rate taking into account specific facts and circumstances |
| ***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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