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New Rules for Listing Pre-revenue Biotech Companies on the Hong Kong Stock Exchange

INTRODUCTION

- The Hong Kong Stock Exchange (the **Exchange**) published its Consultation Conclusions on a Listing Regime for Companies from Emerging and Innovative Sectors on 24 April 2018 (**Consultation Conclusions**) setting out Listing Rule changes which allow the listing on the Exchange of two new categories of company - (i) pre-revenue biotech companies and (ii) innovative and high growth issuers which have weighted voting rights (WVR) structures.

- The new Rules took effect on 30 April 2018 and also create a new secondary listing route for innovative companies with primary listings on Qualifying Exchanges.

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BACKGROUND

- The aim of the Listing Rule changes for pre-revenue biotech companies is to attract listings of China's new generation of biotech companies amid growing competition from the US and Chinese stock exchanges.
- It is hoped that the rule changes will allow the Exchange to overtake NASDAQ within 5 years in terms of the number and market capitalisation of Chinese Biotech listings.
- Media reports suggest that some two dozen Biotech companies are already considering a Hong Kong listing, including:
  - Shanghai Tasly Pharmaceutical plans to raise around US$1 billion
  - Shanghai Henlius Biotech aiming to raise at least US$500 million
  - Hua Medicine seeking to raise at least US$400 million
- The Listing Rule changes aim to attract more listing applicants from the high-growth tech and biotech sectors, the Hong Kong market having been dominated in the past by old economy, low growth sectors, notably the financial and property sectors.
- The financial requirements for listing on the Exchange have acted as a bar to listing biotech companies whose R&D costs typically mean that they do not make profits for some time.

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LISTING PRE-REVENUE BIOTECH COMPANIES

Introduction

- The Exchange has added a new Chapter 18A to the Main Board Listing Rules (**LR**) for the listing of biotech companies which cannot meet the Main Board's financial eligibility tests. Guidance on the factors the Exchange considers in determining listing applicants' eligibility and suitability for listing under the new rules is set out in a new Guidance Letter HKEx-GL92-18 "Suitability for Listing of Biotech Companies" (**the Biotech Guidance Letter**).

Definition of "Biotech Companies"

- Biotech Companies are defined as companies primarily engaged in the research and development (**R&D**), application and commercialisation of Biotech products, processes or technologies.

Biotech - "the application of science and technology to produce commercial products with a medical or other biological application".

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LISTING REQUIREMENTS

Expected market capitalisation

Biotech Companies are required to have a minimum expected market capitalisation of HK$1.5 billion at listing (LR18A.03(2)).

Suitability for listing

In addition to the general requirement that the Exchange must consider the listing applicant and its business to be suitable for listing on the Exchange, Biotech companies must meet the following requirements set out in the Biotech Guidance Letter, to be considered suitable for listing under new Chapter 18A:

a. development of 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 in paragraph 3.3 of the Biotech Guidance Letter;

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LISTING REQUIREMENTS

- The following table sets out a summary of the stages at which different Biotech products are regarded as being beyond the concept stage.

Pharmaceutical (small molecule drugs)	
1. Core products that are new pharmaceutical (small molecule) drugs	Applicant must demonstrate that (a) it has completed Phase I clinical trials – i.e. clinical trials on human subjects categorised as Phase 1 by the FDA (or an equivalent process by another Competent Authority) and (b) the relevant authority has no objection to the commencement of Phase II (or later) clinical trials. Phase II trials are those on human subjects as categorised by the FDA or other Competent Authority.
1. Core products that are pharmaceutical (small molecule drug) products which are based on previously approved products (e.g. the 505(b)(2) application process of the US FDA	Applicant must demonstrate that it has successfully completed at least one clinical trial conducted on human subjects, and that the relevant Competent Authority has no objection for it to commence Phase II (or later) clinical trials.
Biologics	
1. Core Products that are new biologic products	The applicant must demonstrate that it has completed Phase I clinical trials and the relevant Competent Authority has no objection for it to commence Phase II (or later) clinical trials.
1. Core Products that are biosimilar	The applicant must demonstrate that it has completed at least one clinical trial 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.

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LISTING REQUIREMENTS

Medical Devices (including diagnostics)	
Core Products that are medical devices (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; (i) 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 being an institution, body or committee duly authorised or recognised by a Competent Authority or the European Commission for conducting, assessing and supervising clinical trials in the relevant clinical fields. The Exchange has the discretion to recognise other institutions or bodies as Authorised Institutions); 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.
Other Biotech Products	
The Exchange considers other Biotech products on a case by case basis to determine if the applicant has demonstrated that the product has been developed beyond the concept stage by reference to factors referred to in paragraph 3.3 of the Biotech Guidance Letter and whether there is an appropriate framework or objective indicators to make an informed investment decision regarding the listing applicant. A determination to accept such a listing would be a modification that may only be made with the SFC's consent under LR2.04. For applicants eligible to list under Chapter 18A, references to "Core Products" refer to the Biotech Product of the relevant listing applicant.	

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LISTING REQUIREMENTS

b. primary engagement in R&D for developing its Core Product(s);

c. engagement in the R&D of its Core Products for a minimum of 12 months prior to listing (and in the case of a Core Product which is in-licensed or acquired from third parties, the listing applicant must be able to demonstrate R&D progress since the in-licensing acquisition);

d. the primary reason for listing must be the raising of finance for R&D to bring its Core Product(s) to commercialisation;

e. the applicant must have registered patent(s), patent application(s) and/or intellectual property in relation to its Core Product(s);

f. if the applicant is engaged in R&D of pharmaceutical (small molecule drugs) products or biological products, there must be a pipeline of those potential products; and

g. prior meaningful third party investment (being more than just a token investment) from at least one sophisticated investor at least six months before the proposed listing, and that investment continuing at listing. In the case of a spin-off listing from a parent company, the Exchange may not insist on compliance with this requirement where the applicant can otherwise demonstrate a reasonable degree of market acceptance for its R&D and Biotech Product.

LISTING REQUIREMENTS

- The Exchange assesses on a case-by-case basis whether an investor is a "sophisticated investor" for these purposes by reference to factors such as net assets and assets under management, relevant investment experience, and the investor's knowledge and expertise in the relevant field. The Biotech Guidance Letter (paragraph 3.2(g)(i)) gives the following as examples of sophisticated investors:

    a. a dedicated healthcare or Biotech fund or an established fund with a division/department that invests in the biopharmaceutical sector;
    b. a major pharmaceutical/healthcare company;
    c. a venture capital fund of a major pharmaceutical/healthcare company; and
    d. an investor, investment fund or financial institution with minimum assets under management of HK$1 billion (increased from the HK$500,000 originally proposed).

- Whether a third party investment is meaningful is assessed case-by-case taking into account the nature of the investment, the amount invested, the size of the stake and timing of the investment. As an indicative benchmark, the Exchange gives the following as examples of investment amounts that are typically considered to be "meaningful investments":

Applicant's market capitalisation	Meaningful investment - % of the applicant's issued share capital on listing
HK$1.5 bln - HK$3 bln	5% or more
HK$3 bln - HK$8 bln	3% or more
> HK$8 billion	1% or more

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LISTING REQUIREMENTS

Track Record

- Biotech Company listing applicants must have a track record of operating in their current line of business of at least 2 financial years prior to listing under substantially the same management (LR 18A.03(3)).

Ownership Continuity and Control

- The Exchange reviews any change in the applicant's ownership within 12 months prior to the date of the listing application in assessing the applicant's suitability for listing (Paragraph 4.1 of the Biotech Guidance Letter).

Working capital

- An applicant must have available working capital to cover at least 125% of the group's costs for at least 12 months from the date of publication of the listing document (after taking into account the IPO proceeds) (LR 18A.03(4)). These costs should substantially consist of (a) general, administrative and operating costs, and (b) R&D costs. The Exchange expects a substantive portion of the IPO proceeds to be applied to these costs.

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LISTING REQUIREMENTS

Subscription of shares by existing shareholders

- Biotech Companies which list under Chapter 18A are expected to have significant ongoing funding needs to bring their Core Product(s) to commercialisation. Existing shareholders in Biotech Company listing applicants may wish to continue to participate in post-listing fundraisings to prevent their shareholdings being diluted. Given the likely funding needs of Biotech Companies and the important role played by existing shareholders in providing continuing funding, existing shareholders are allowed to participate in a Biotech Company's IPO, provided that the company complies with the public float requirements of LR 8.08(1) and LR18A.07.

Public Float - Restriction on cornerstones

- Shares allocated to cornerstone investors are not taken into account in determining whether a Biotech Company has met the minimum 25% initial public float requirement under Listing Rule 8.08(1) on initial listing and up to the expiry of the six-month lock up period for cornerstone investors.

- Existing shareholders are allowed to subscribe for IPO shares to avoid their shareholdings being diluted under HKEx Guidance Letters 43-12 and 85-16. Existing shareholders who cannot satisfy the conditions under current guidance for subscribing for IPO shares, can participate in the IPO of a Biotech Company as a cornerstone investor.

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LISTING REQUIREMENTS

- IPO shares subscribed by existing shareholders do not count towards the public float. However, shares subscribed before the IPO by existing shareholders who are not core connected persons or not recognised as a member of the public under LR8.24, count towards the public float.

- Due to concerns on the restrictions on cornerstone investors raised by respondents to the Consultation Paper, the Exchange has decided to allow some flexibility for Biotech Companies whose market capitalisation exceeds the minimum HK$1.5 billion required.

- Biotech listing applicants are required to have a minimum public float of 25% representing HK$375 million of public float at listing. That public float must be achieved without including subscriptions by the company's existing shareholders and subscriptions by cornerstone investors.

- Provided a listing applicant can meet this requirement, cornerstone investments and existing shareholders' subscriptions can be included in determining the company's public float, provided that the existing shareholders and cornerstone investors are not core connected persons of the company or otherwise are not recognised as members of the public under LR8.24.

Connected Person's Post-Listing Anti-Dilution rights

- Respondents to the Consultation Paper raised concerns that substantial shareholders (i.e. holders of 10%) of Biotech Companies would be prevented by the Exchange's connected transaction rules from avoiding dilution of their shareholdings by subscribing for shares in a post-listing share offering. They considered this could be problematic for Biotech Company listing applicants that are likely to have significant ongoing funding needs to develop Core Product(s) to commercialisation and that existing investors would likely want to participate in post-listing fund raisings to prevent a dilution of their shareholdings.

- A substantial shareholder is a "connected person" under Chapter 14 of the Listing Rules. Although there is an exemption for issues of new shares to existing shareholders, this only applies to pro rata issues to existing shareholders. Thus a non-pro rata issue to a connected person would be conditional upon shareholders' approval and any shareholder with a material interest in the transaction would be required to abstain from voting.

- While the Exchange acknowledges that Biotech companies are likely to have significant ongoing funding needs, it also notes that an issue of shares to a substantial shareholder is allowed provided it is approved by shareholders who do not have a material interest in the transaction. It does not therefore propose to change the Listing Rules at this stage, but will monitor developments and consider whether a further review is necessary in future.

ENHANCED DISCLOSURE REQUIREMENTS

- Biotech applicants must provide enhanced risk disclosure in listing documents, including information relating to:
  a. their strategic objectives;
  b. details of each Core Product, including:
     - a description of the Core Product;
     - details of any relevant regulatory approval required and/or obtained for each Core Product;
     - a summary of material communications with the relevant Competent Authority in relation to its Core Product(s) (unless disclosure is not permitted under applicable laws or regulations, or the directions of the Competent Authority);
     - the stage of research and development for each Core Product;
     - development details by key stages and its requirements for each Core Product to reach commercialisation, and a general indication of the likely timeframe, if the development is successful, for the product to reach commercialisation;
     - all material safety data relating to its Core Product(s), including any serious adverse events;
     - a description of the immediate market opportunity of each Core Product if it proceeds to commercialization and any potential increased market opportunity in the future (including a general description of the competition in the potential market);

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ENHANCED DISCLOSURE REQUIREMENTS

- details of patent(s) granted, registered 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;
- in the case of a Core Product which is biologics, disclosure of planned capacity and production related technology details; and
- to the extent that any Core Product is in-licensed, a clear statement of the issuer's material rights and obligations under the applicable licensing agreement;

c. a statement that no material unexpected or adverse changes have occurred since the date of issue of the relevant regulatory approval for a Core Product (if any). Any material changes must be prominently disclosed;

d. a description of any Approved Products owned by the listing applicant and the length of unexpired patent protection period and details of current and expected market competitors;

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ENHANCED DISCLOSURE REQUIREMENTS

e. details of the Biotech Company's R&D experience including:
   - details of its operations in laboratory R&D;
   - the collective expertise and experience of key management and technical staff; and
   - its collaborative development and research agreements;

f. details of the relevant experience of the Biotech Company's directors and senior management in the research and development, manufacturing and commercialisation of Biotech Products;

g. the salient terms of any service agreements between the listing applicant and its key management and technical staff;

h. measures (if any) that the applicant has in place to retain key management or technical staff (e.g. incentivisation arrangements and/or non-compete clauses), and the safeguards and arrangements that the applicant has in place, in the event of the departure of any of its key management or technical staff;

i. a statement of any legal claims or proceedings that may have an influence on its research and development for any Core Product;

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ENHANCED DISCLOSURE REQUIREMENTS

j. disclosure of specific risks, general risks and dependencies, including:

- potential risks in clinical trials;
- risks associated with the approval process for its Core Product(s); and
- the extent to which its business is dependent on key individuals and the impact of the departure of key management or technical staff on the applicant's business operations;

k. if relevant and material to the Biotech Company's business operations, information on:

- project risks arising from environmental, social, and health and safety issues;
- compliance with host country laws, regulations and permits, and payments made to host country governments in respect of tax, royalties and other significant payments on a country by country basis;
- its historical experience of dealing with host country laws and practices, including management of differences between national and local practice; and
- its historical experience of dealing with the concerns of local governments and communities on the sites of its research and trials, and relevant management arrangements;

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ENHANCED DISCLOSURE REQUIREMENTS

l. an estimate of cash operating costs, including costs related to R&D and clinical trials incurred in the development of the Core Products and costs associated with:

- workforce employment;
- direct production costs, including materials (if it has commenced production);
- R&D;
- product marketing (if any);
- non-income taxes, royalties and other governmental charges (if any);
- contingency allowances; and
- any other significant costs.

In particular, Biotech Companies are required to: (a) set out the components of cash operating costs separately by category; (b) explain the reason for any departure from the list of items to be included under cash operating costs; and (c) discuss any material cost items that should be highlighted to investors;

m. if the applicant has obtained an expert technical assessment, that assessment should be included in the listing document where relevant and appropriate; and

n. listing documents must include a prominent warning statement in respect of each Core Product that it may not ultimately be successfully developed and marketed.

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CONTINUING OBLIGATIONS OF LISTED BIOTECH COMPANIES

Financial Report Disclosure

- Biotech Companies must disclose in their annual and half-year reports details of R&D activities including:
    a. details of the key stages of each of its Core Products under development to reach commercialisation and a general indication of the likely timeframe for it to reach commercialisation;
    b. a summary of expenditure incurred on R&D activities; and
    c. a prominently disclosed warning that a Core Product may not ultimately be successfully developed and marketed.

Delisting

- The Exchange has the power to suspend dealings in the shares of a Biotech Company which does not maintain sufficient operations or assets as required by LR13.24, or may cancel its listing under LR6.01. The Exchange can also give a company up to 12 months to comply with LR13.24, after which its listing will be cancelled if it is still in breach (LR18A.09).

Prohibition on fundamental change in business

- Listed Biotech Companies require the Exchange's consent for any acquisition, disposal or other transaction or arrangement (or a series of such transactions) that would result in a fundamental change to the company's principal business activities as described in its listing document (LR18A.10).

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CONTINUING OBLIGATIONS OF LISTED BIOTECH COMPANIES

Stock Marker

- Stock names of listed Biotech Companies have the marker "B" at the end of their name (LR18A.11).

Meeting the Main Board financial eligibility tests

- Once a listed Biotech Company is able to satisfy the financial eligibility tests under LR 8.05, LR 18A.09 to LR18A.11 will cease to apply (i.e. sufficiency of operations, Exchange's consent requirement for material change in business and stock marker requirement).

- Biotech companies are a new sector for Hong Kong listings having previously been prevented from listing by the financial eligibility requirements for profits, revenue and cash flow. The first listings of Biotech companies are expected to occur as early as summer 2018 and there is already a pipeline of Biotech companies that have expressed an interest in listing in Hong Kong. Applicants have been able to submit listing applications since 30 April 2018.

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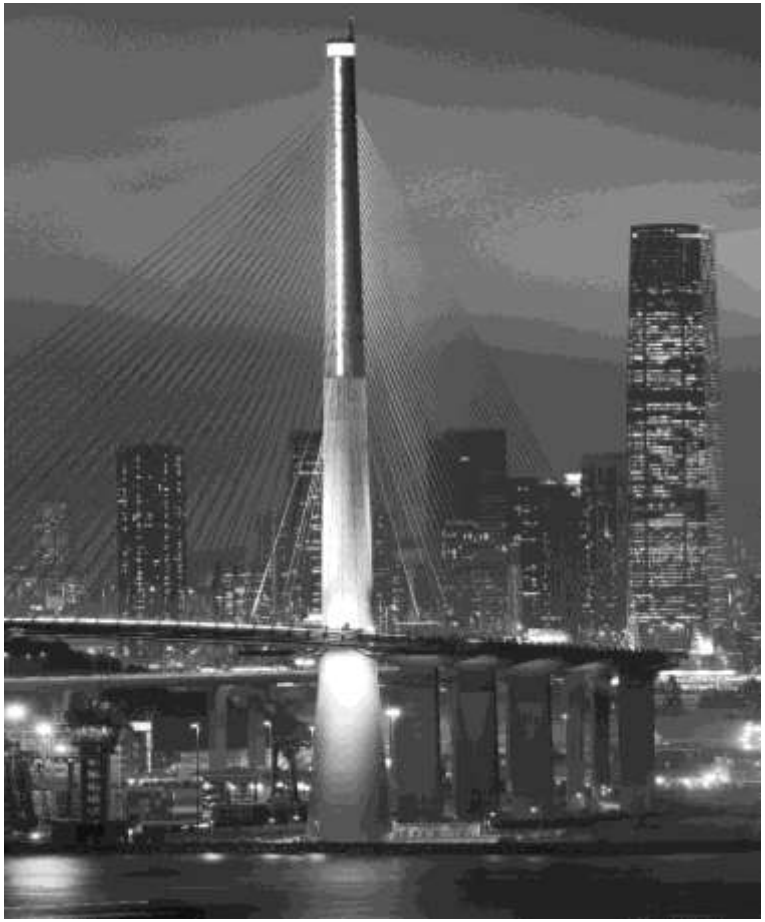

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