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# WHITE PAPER

March 2018

## Hong Kong Exchange Publishes Draft Rules for Biotech Listings, Requests Comments

The Hong Kong Stock Exchange recently published a Consultation Paper on a Listing Regime for Companies from Emerging and Innovative Sectors, and proposed to introduce a new chapter implementing the listing of pre-revenue/pre-profit biotech companies on the Main Board of the Exchange.

The Consultation Paper clarifies uncertainties in the previous proposal (particularly on determining whether a product has been developed beyond the concept stage) and enables biotech companies seeking listing in Hong Kong to effectively assess if they could meet the relevant requirements.

This Jones Day *White Paper* reviews key points in the Consultation Paper.

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The Stock Exchange of Hong Kong Limited ("Exchange") published the Consultation Paper on a Listing Regime for Companies from Emerging and Innovative Sectors on February 23, 2018 ("Consultation Paper"), and proposed to introduce a new chapter ("Chapter 18A") to the Main Board Listing Rules ("Listing Rules") to implement the proposal of allowing the listing of pre-revenue/pre-profit biotech companies on the Main Board of the Exchange ("Main Board").

The Consultation Paper clarifies uncertainties in the previous proposal (particularly on determining whether a product has been developed beyond the concept stage) and enables biotech companies seeking listing in Hong Kong to effectively assess if they could meet the relevant requirements.

This Jones Day *White Paper* reviews key points in the Consultation Paper.

## DEFINING "BIOTECH," "BIOTECH PRODUCT," AND "BIOTECH COMPANY"

According to the draft Chapter 18A to the Listing Rules ("Draft Chapter 18A"), "Biotech" means "the application of science and technology to produce commercial products with a medical or other biological application." "Biotech Product" means "biotech products, processes or technologies." "Biotech Company" means "a company primarily engaged in the research and development, application and commercialization of Biotech Products."

## DETERMINING A PRE-REVENUE BIOTECH COMPANY'S ELIGIBILITY AND SUITABILITY TO LIST

The Exchange proposes to consider the Biotech Companies that do not meet any financial eligibility tests under the current Listing Rules to be eligible and suitable to list pursuant to Chapter 18A, if such Biotech Companies can demonstrate the following features:

(a) The Biotech Company must have developed 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 (see below for specific analysis);

(b) The Biotech Company must have developed 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 (see below for specific analysis);

(c) It must have been engaged with the R&D of its Core Product(s) for a minimum of 12 months prior to listing;

(d) It must have as its primary reason for listing the raising of finance for R&D to bring its Core Product(s) to commercialization;

(e) If the applicant is engaged in the R&D of pharmaceutical (small molecule drugs) products or biologic products, it must demonstrate that it has a pipeline of those potential products; and

(f) It must have previously received meaningful third party investment (being more than just a token investment) from at least one Sophisticated Investor at least six months before the date of the proposed listing which must remain at IPO. The Exchange may not require compliance with this factor where the applicant is a spin-off from a parent company if the applicant is able to otherwise demonstrate to the Exchange's satisfaction that a reasonable degree of market acceptance exists for its R&D and Biotech Product (for example, in the form of collaboration with other established R&D companies).

## CONDITIONS FOR A REGULATED PRODUCT TO BE CONSIDERED DEVELOPED BEYOND THE CONCEPT STAGE

The Exchange proposes that a regulated product would be considered to have been developed beyond the concept stage under the following circumstances:

(a) Pharmaceutical (small molecule drugs)

(i) In the case of a Core Product that is a new pharmaceutical (small molecule drug) product, the applicant must demonstrate that it has completed Phase I clinical trials and that the relevant Competent Authority has no objection for it to commence Phase II (or later) clinical trials.

(ii) In the case of a Core Product that is a pharmaceutical (small molecule drug) product which is based on previously approved products (for example, the FDA's 505(b)(2) application process in the US), the applicant must demonstrate that it has successfully completed at least one clinical trial conducted on human subjects, and the relevant Competent Authority has no objection for it to commence Phase II (or later) clinical trials.

(b) Biologics

(i) In the case of a Core Product that is a new biologic product, 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.

(ii) In the case of a Core Product that is a biosimilar, the applicant must demonstrate that it has completed at least one clinical trial conducted 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.

(c) Medical devices (including diagnostics)

In the case of a Core Product that is a medical device (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;

(ii) 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); 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 has no objection for the applicant to commence sales of the device.

(d) Other Biotech Products

(i) The Exchange will consider Biotech Products which do not fall into the above criteria on a case by case basis to determine if an applicant has demonstrated that the relevant Biotech Product has been developed beyond the concept stage by reference to, amongst other things, the factors described above in this paragraph, and whether there is an appropriate framework or objective indicators for investors to make an informed investment decision regarding the listing applicant. A determination to accept such a listing application would be a modification that may only be made with the consent of the Securities and Futures Commission ("SFC") under Rule 2.04.

In the Draft Chapter 18A, the Exchange only recognizes U.S. Food and Drug Administration ("FDA"), China Food and Drug Administration ("CFDA") and European Medicines Agency ("EMA") as competent authorities ("Competent Authorities"). The Exchange may, at its discretion, recognise other national or supranational authorities as Competent Authorities in individual cases (depending on the nature of the Biotech Product). The Exchange will seek the SFC's consent before making such a recognition.

The guidance above are not set forth in the Draft Chapter 18A. The Exchange emphasizes that the factors above are neither exhaustive nor binding, and the Exchange will take into account all relevant circumstances in its assessment of the suitability of an applicant for listing. The Exchange will retain the discretion to find that an applicant is not suitable for listing even if it satisfies the above factors.

## WHAT ARE THE REGULATIONS ON EXPECTED MARKET CAPITALIZATION?

The Exchange proposes that a listing applicant under Chapter 18A must have a minimum expected market capitalisation at the time of listing on the Exchange of HK$1.5 billion.

## WHAT ARE THE REGULATIONS ON TRACK RECORD?

The Exchange requests that a Biotech Company applicant must have been in operation in its current line of business for at least two financial years prior to listing under substantially the same management.

## WHAT ARE THE WORKING CAPITAL REQUIREMENTS?

A listing applicant under Chapter 18A is required to have available working capital to cover at least 125 percent of the group's cost for at least the next 12 months (after taking into account the proceeds of the new applicant's initial listing). These costs must substantially consist of general, administration and operation costs and R&D costs. The Exchange also expects that a substantive portion of the IPO proceeds will be used to cover these costs.

## WHAT ARE THE ADDITIONAL DISCLOSURE REQUIREMENTS ON LISTING DOCUMENTS OF BIOTECH COMPANIES?

A listing applicant under Chapter 18A is required to provide a prominent warning statement and enhanced risk disclosures. Specific additional disclosure requirements are set forth in Rule 18A.04 of the Draft Chapter 18A, including disclosures on:

(a) The phases of development for its Core Product(s);

(b) Material communications with all relevant Competent Authorities in relation to its Core Product(s) (unless disclosure is restricted under applicable laws or regulations or the direction of the Competent Authority);

(c) All material safety data relating to its Core Product(s);

(d) The immediate market opportunity and any potential increased market opportunity of its Core Product(s);

(e) Its rights and obligations in respect of any in-licensed Core Products;

(f) Disclosure of operating costs, capital expenditure and working capital including details of spending on R&D;

(g) Patents granted, registered and applied for and other intellectual properties relating 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); and

(h) The R&D experience of management.

Biotech Companies would also be required to provide ongoing disclosures regarding their R&D activities in the interim and annual reports.

## WHAT ARE THE RESTRICTIONS ON CORNERSTONE INVESTORS?

The Exchange proposes that shares subscribed by cornerstone investors will not be counted towards determining whether the Biotech Company has met the minimum initial public float requirement at the time of listing and at all times prior to the expiration of the six-month lock-up period from the date of listing that applies to shares subscribed by cornerstone investors in the IPO. The Exchange considers that the proposed restriction on cornerstone investors will help reduce the influence of pre-arranged deals on the book-building process and will help ensure that the pricing process for the IPOs of such companies is as market-driven as possible.

Existing shareholders of the applicant may subscribe for shares in the IPO to avoid a dilution to their shareholdings under the existing regulations. Where an existing shareholder does not meet the conditions under the existing guidance, the Exchange is proposing to allow such a shareholder to participate in the IPO of a Biotech Company as a cornerstone investor. If the existing shareholder is not a core connected person or otherwise not recognized by the Exchange to be a member of the public in accordance with Rule 8.24, shares subscribed by existing shareholders in the IPO will not be counted towards determining whether the Biotech Company has met the minimum initial public float requirement, but any shares held by

such existing shareholders prior to the IPO will be counted towards the public float.

## WHAT ARE THE OTHER MEASURES TO MANAGE RISKS ASSOCIATED WITH BIOTECH COMPANIES?

The Exchange proposes that a Biotech Company listed under Chapter 18A would not be allowed to effect any acquisition(s), disposal(s) or other transaction(s) or arrangement(s) that would result in a fundamental change to its principal business without the Exchange's prior consent. However, the Exchange emphasizes that such prior consent will normally be given if such Biotech Companies can satisfy the Exchange that they are engaging in a legitimate business expansion or diversification that forms part of its business strategies.

The Exchange also proposes that a Biotech Company listed under Chapter 18A will be governed by the existing de-listing Rules except where the Exchange considers that such an issuer has failed to meet its continuing obligation to maintain sufficient operations or assets. Under these circumstances, the Exchange will give the issuer a period of up to 12 months to re-comply with the requirement. If such issuer fails to do so, the Exchange will cancel its listing.

The Exchange will require Biotech Companies listed under Chapter 18A to be prominently identified through a unique stock marker "B" at the end of their stock name.

## CONCLUSIONS

The consultation period will end on March 23, 2018. If everything goes smoothly, the new regime is expected to formally take effect by the end of this April.

The Exchange's decision to allow pre-revenue biotech companies to be listed on the Main Board is a breakthrough in the previous regulatory perspective and an important step towards keeping abreast of market development. It is anticipated that this new regime will enhance Hong Kong's attractiveness as a leading fundraising market in the world, and enhance Hong Kong's position as a leading international financial center. This is undoubtedly a significant milestone in the capital market of Hong Kong

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