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# Client Alert

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# Pre-revenue biotech companies can apply for listing in Hong Kong with effect from 30 April 2018

## Current position

On 24 April 2018, The Stock Exchange of Hong Kong Limited (HKEx) published its *Consultation Conclusions to HKEx's proposals to expand Hong Kong's listing regime to facilitate the listing of emerging and innovative companies* (the "**Conclusion**"). On 30 April 2018, the new listing rules and the three relevant guidance letters will take effect and HKEx will start to accept listing applications filed under the following three new chapters in the Main Board Listing Rules:

a) Chapter 8A - permits listings of innovative companies with weighted voting rights (WVR) structures;

b) Chapter 18A - permits listings of pre-revenue biotech companies that do not satisfy any of the financial eligibility tests; and

c) Chapter 19C - establishes a new concessionary secondary listing route for innovative companies that have their primary listings on the New York Stock Exchange, Nasdaq or the Main Market of the London Stock Exchange (Premium).

**This client alert will focus on the listings of pre-revenue biotech companies. For innovative companies, please refer to the innovative company client alert.**

## Why the biotech sector is exempted from the traditional financial eligibility test?

HKEx recognizes the legitimate capital raising needs and tangible commercial value of the biotech sector before reaching a revenue-generating stage with reference to the following trends:

a) listings of early stage pre-revenue biotech companies in the US;

b) the biotech sector is strictly regulated and developed under an external milestone regime;

c) breakthroughs in global biotech innovation;

d) an aging population worldwide, particularly in China; and

e) China's biotech industry reform.

As compared to other innovative and emerging sectors, the biotech sector is distinctive in terms of product regulations and the significant capital requirements for research and development (R&D) during the multiple stages of the regulatory approval process. As such, HKEx considers it suitable to exempt the biotech sector from the traditional financial eligibility tests

specified in rule 8.05 and expand the listing regime to satisfy the varying financial needs of pre-revenue biotech companies.

## What are the key features of eligible biotech companies?

HKEx will consider the following factors when determining a biotech company's eligibility and suitability to list without satisfying the traditional financial eligibility tests specified in rule 8.05.

### Core products

A core product forms the basis of a biotech company's listing application and such core product must be evaluated and approved by one of the specified competent authorities (see below) before it can be marketed and sold.

At the time of the listing application, a biotech company must have developed at least one core product beyond the concept stage. The developmental milestones for four different kinds of biotech products are summarized as follows:

| ***Core products*** | ***External developmental milestone*** |
|---|---|
| Pharmaceutical (small molecule drugs) | • Phase I clinical trials completed; and<br>• Competent Authority has no objection to commence Phase II clinical trials. |
| Biologics | |
| Medical Devices (including diagnostics) | • At least one clinical trial on human subjects has been completed;<br>• The product is classified as a Class II medical device or above; and<br>• Competent Authority has no objection to the applicant proceeding to further clinical trials or commencing sales. |
| Other Biotech Products | • HKEx will consider other biotech products on a case-by-case basis to determine if the core product has been developed beyond the concept stage. |

### Competent Authorities

HKEx recognizes the following three authorities in the US, China and Europe as competent authorities to evaluate and approve core products:

- US Food and Drug Administration (FDA)
- China Food and Drug Administration (CFDA)
- European Medicines Agency (EMA)

HKEx has the discretion to recognize other national or supranational authorities on a case-by-case basis.

## Research and Development

A biotech company must have been engaged with the R&D of its core products for a minimum of 12 months before listing. In addition, the primary reason for listing must be fundraising for the R&D and commercialization of its core products.

For R&D of pharmaceutical products (small molecule drugs) or biologic products, the biotech company must demonstrate a pipeline of those potential products.

## Meaningful Third Party Investments from a Sophisticated Investor

To demonstrate market acceptance of a core product, a biotech company must have received meaningful investment from at least one investor who is considered as sophisticated with reference to such investor's net assets, experience, knowledge and expertise. Such investment must be made at least six months before the date of the proposed listing and remain at IPO. In the case of a spin-off company, this requirement may be waived if the applicant can demonstrate a reasonable degree of market acceptance for its R&D and the core product.

## Patents

A biotech company must have registered patents, patent applications and/or intellectual properties in relation to its core products.

## Others Listing Requirements

In addition, a biotech company must satisfy the following listing requirements:

| | |
|---|---|
| Minimum market capitalization | HK$1.5 billion (approximately US$190 million) at the time of listing |
| Track record | Operate in the same business under substantially the same management for at least two financial years |
| Working capital | 125% of the group's costs for a minimum of 12 months |
| Cornerstone investors | Shares allocated to a cornerstone investor will not be counted towards the minimum public float requirement (25% as a general requirement) at the time of listing and in the first six months after listing |

## Shareholder Protections

HKEx may suspend dealings or cancel the listing of a pre-revenue biotech company if it fails to comply with the sufficient operations requirements under rule 13.24, subject to a 12 months remedial period to re-comply with the rule.

Without the prior consent of the HKEx, a pre-revenue biotech company cannot effect any transaction that will result in a fundamental change of its principal business.

# What are the major differences between the Proposal and the Conclusion?

HKEx implements the new listing rules broadly as proposed. The major differences between the proposed amendments in the consultation paper released on 23 February 2018 ("**Proposal**") and the Conclusion are summarized below:

| **Differences** | **Proposal** | **Conclusion** |
|---|---|---|
| Suitability for listing | See the above section titled "What are the key features of eligible biotech companies?" | Add R&D progress for any core product that is in-licensed or acquired |
| Definition of "sophisticated investor" | With reference to such investor's net assets, experience, knowledge and expertise | More guidance and examples are provided. Examples include a dedicated healthcare fund, a major healthcare company and an investor with minimum assets under management of HK$1 billion |
| Definition of "meaningful investment" | More than just a token investment | Add indicative benchmark investment for different amount of market capitalization |
| Excluding cornerstone investors from the public float (Rule 18A.07) | Shares allocated to a cornerstone investor will not be counted towards the minimum public float requirement | Cornerstones can be counted towards public float if there is at least HK$375 million of public float (excluding cornerstones) at the time of listing |
| Patents | Including durable patents | Excluding durable patents |
| Disclosures on measures to retain key personnel and capacity of biologics (Rule 18A.04) | Nil | Specify the disclosures on measures to retain key personnel and capacity of biologics |

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