# Hong Kong Launches New Rules on Biotech Listings

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The Stock Exchange of Hong Kong Limited (the **Exchange**) has concluded its consultation on a listing regime for emerging and innovative companies and finalised the related Hong Kong Listing Rules and guidance letters.

From 30 April 2018, biotech companies that are pre-revenue are permitted to list under a new chapter (the **Biotech Chapter**) in the Main Board Listing Rules (the **Listing Rules**).

The Exchange defines biotech companies as companies primarily engaged in the research and development (**R&D**), application and commercialisation of products, processes or technologies in the biotech sphere. Biotech companies have been singled out for special treatment by the Exchange as they tend to be strictly regulated under a regime that sets external milestones on development progress. At present, the Exchange recognises the US FDA (the **FDA**), the China FDA and the European Medicines Agency as competent authorities for the purpose of the Biotech Chapter, and it may recognise other national and supranational authorities on a case-by-case basis with the consent of the Securities and Futures Commission (**SFC**).

## Listing criteria under the Biotech Chapter

The Exchange has indicated that an applicant applying for listing under the Biotech Chapter must demonstrate that it is a biotech company and would normally be expected to have the following features:

### 1 *Biotech applicants should have developed at least one core product beyond the concept stage*

The Exchange requires the biotech applicant to have developed at least one core product that has proceeded beyond the concept stage. The Exchange considers 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.

#### A. For pharmaceutical (small molecule drugs) products

The biotech applicant must demonstrate that it has completed Phase I clinical trials as defined by the FDA or an equivalent process defined by other regulators (**Phase I clinical trials**) and that the relevant regulator has no objection for it to commence Phase II or later clinical trials as defined by the FDA or an equivalent process defined by other regulators (**Phase II clinical trials**). For a product which is based on a previously approved product, such as a product which is eligible for 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 that the relevant regulator has no objection for it to commence Phase II or later clinical trials.

#### B. For biologic products

The biotech applicant must demonstrate that it has completed Phase I clinical trials and that the relevant regulator has no objection for it to

commence Phase II or later clinical trials. For biosimilar products, the applicant must demonstrate that it has completed at least one clinical trial conducted on human subjects and that the relevant regulator has no objection for it to commence Phase II or later clinical trials to demonstrate bio-equivalency.

**C. For medical devices (including diagnostics)**

The biotech applicant must demonstrate that the product is categorised as a Class II medical device or above as defined by the FDA or an equivalent device defined by other regulators and that it has completed at least one clinical trial on human subjects and the regulator has endorsed or not expressed objection for the application to proceed to further clinical trials or sales of the device.

**D. For other biotech products**

The Exchange will consider biotech products which do not fall into the above categories on a case-by-case basis to determine whether such products have been developed beyond the concept stage. One of the important factors the Exchange will consider is whether there is an appropriate framework or objective indicators for investors to make an informed investment decision regarding the biotech applicant. The SFC's approval would also be required in these circumstances.

**2** ***Biotech applicants should have minimum expected market capitalisation of HK$1.5 billion at the time of listing***

The minimum market capitalisation is intended to limit applicants to those biotech companies that have achieved a higher degree of investment from pre-IPO investors on the basis of confidence that the company and its management have the capability to achieve success in their R&D activities.

**3** ***Biotech applicants must focus on R&D of their core product(s)***

The Exchange requires the biotech applicant to have been primarily engaged in R&D for the purposes of developing its core product(s).

**4** ***Biotech applicants must meet the minimum R&D period requirement for their core product(s)***

The Exchange requires the biotech applicant to have been engaged in the R&D of its core product(s) for a minimum of 12 months prior to its listing and, for core products that are in-licensed or acquired, to demonstrate some R&D progress since the in-licensing / acquisition.

**5** ***The primary reason for the listing must be to raise funds for R&D***

The Exchange requires that the primary reason for the listing of the biotech applicant under the new chapter is to finance its R&D to bring its core product(s) to commercialisation.

**6** ***Biotech applicants must have sufficient IP in relation to their core product(s)***

The Exchange requires the biotech applicant to have patent(s), registered patent(s), patent application(s) and/or intellectual property in relation to its core product(s).

Although it is not mandatory for the applicant to itself possess the patent in relation to the core product (e.g. it may be in-licensed), the Exchange will assess whether it owns a sufficient portfolio of other IP rights (e.g. copyright and trade secrets).

**7** ***Certain types of biotech applicants should have more than one potential product under development***

If a biotech applicant is engaged in the R&D of pharmaceutical (small molecule drugs) products or biologic products, the Exchange requires the biotech applicant to have a pipeline of potential products.

### 8 *Biotech applicants should have previously received meaningful investment from at least one sophisticated investor at least six months before the date of the listing and which must remain at IPO*

This feature is intended to demonstrate that a reasonable degree of market acceptance exists for the applicant's R&D and its products.

"Sophisticated investor" and "meaningful investment" will be assessed on a case-by-case basis. Some examples of investors and levels of investment that would generally qualify include: a healthcare or biotech-specific fund, a major pharmaceutical or healthcare company, or an investor with an AUM of at least HK$1 billion; and an investment of 5% (if market capitalisation is HK$1.5 billion to HK$3 billion), 3% (if market capitalisation is HK$3 billion to HK$8 billion) and 1% (if market capitalisation is more than HK$8 billion) of the applicant's issued share capital at IPO.

### 9 *Biotech applicant must meet the minimum public float requirement, of which HK$375 million must be exclusive of subscriptions by cornerstone and existing shareholders*

In addition to the usual 25% public float requirement, the Exchange requires that at least HK$375 million of an applicant's public float at IPO is held by the public exclusive of IPO shares subscribed by cornerstone and existing investors. As long as the applicant is able to meet this requirement, the Exchange allows cornerstone investments and subscriptions by existing shareholders to be included in the determination of the applicant's public float (provided those investors are not core connected persons or otherwise not considered as members of the public under Listing Rule 8.24). This is to facilitate a more market driven book-building process for a pre-revenue applicant.

### 10 *Biotech applicants must meet enhanced working capital requirements*

Biotech applicants must meet enhanced working capital requirements set out by the Exchange (*i.e.*, 125% of the applicant's current requirements over the next 12 months).

### 11 *Biotech applicants must meet the minimum operation period in their current business*

Biotech applicants must have been in operation in their current line of business (for example, R&D in biotech) for at least two financial years prior to listing. The Listing Document should contain at least two financial years of audited financial statements and ownership continuity will be assessed by reference to the period of 12 months prior to the listing application.

### 12 *Biotech applicants must provide enhanced disclosure*

In order to ensure that investors are fully informed of the relevant business and R&D risks, biotech companies will also be required to provide enhanced disclosure in their listing documents, including:

a) enhanced risk disclosures;
b) disclosures on the phases of development for their product(s) and the potential market of their product(s);
c) disclosure of details of spending on R&D;
d) disclosure of details of patents granted and applied for; and
e) disclosure of details of the R&D experience of management and measures put in place to retain key personnel.

Issuers will be required to disclose similar details in their interim and annual reports.

*The new listing rules under the Biotech Chapter come into effect on 30 April 2018. A Biotech Advisory Panel consisting of industry experts will be established to advise the Exchange (on an "as needed" basis) in its review of biotech listing applications.*

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