# Is Hong Kong's Listing Regime for Biotech Companies Viable? – Practicalities for Giving Credence to Listings under the New Chapter 18A of the Listing Rules

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## Background

As an initiative to maintaining its competitiveness, The Stock Exchange of Hong Kong Limited (**SEHK**) has implemented a number of changes to the main board listing rules (**Listing Rules**) in order to, among other things, attract quality pre-revenue biotech firms to list in the bourse of Hong Kong. The new rules and requirements for such biotech firms to be listed are set out in the new Chapter 18A of the Listing Rules, as reported in our Financial Services Regulatory Update of April 27, 2018 published on our website (please see https://www.jmaklegal.com/category/publications/fs-regulatary-update).

The new listing regime for biotech companies set up by SEHK signifies the exchange's ambition. According to its chief executive, Charles Li Xiaojia, SEHK plans to overtake New York's Nasdaq within five years in terms of mainland Chinese biotechnology firms' listings and their market capitalization.

## The Pre-existing Financial Requirements

As specified in Chapter 8 of the Listing Rules, an applicant for listing on the main board normally has a choice of three tests in order to satisfy the financial eligibility for listing, namely, the profit test, the market capitalization/revenue/cash flow test and the market capitalization/revenue test. All of these tests carry the same important feature - a track record of either profits or revenue must be demonstrated. The new regime for biotech companies deviates from this basic financial requirement.

## Benefits and Risks Associated with Pre-revenue Biotech Companies

The underlying rationale of the financial eligibility tests under Chapter 8 is to provide a benchmark for the investors to judge the financial condition and future prospects of companies, so as to enable them to make informed investment decisions on those companies. As the investing public at large are generally not equipped with the skills of investment professionals and do not possess sufficient expertise to assess the profitability of a listed company, relevant rules and regulations must be put in place to safeguard their interests.

While it is recognized that pre-revenue biotech companies have the potential of generating high revenues and profits, there are also inherent risks associated with these companies given that their prospect of success could be hugely dependent upon their R&D capabilities, the commercialization of their products and

outstanding approvals or authorizations yet to be obtained from relevant regulatory authorities.

## Practicalities Regarding the New Chapter 18A

1. ***Biotech functionalities verification – "approved products"***

   In light of the uncertainties associated with biotech companies due to their predominantly pre-revenue and immature nature, the provisions under Rule 18A.04(2)(c) and (4) of the Listing Rules specify that the listing applicants must disclose details of any relevant regulatory approval required and a description of approved products developed by the applicant. As defined in Chapter 18A.01 of the Listing Rules, the US Food and Drug Administration (**FDA**), the China Food and Drug Administration (**CFDA**) and the European Medicines Agency (**EMA**) are the 3 competent authorities that are recognized to sign off for approved products. This is believed to provide protection to investors as this is supposed to offer globally recognized benchmarks to investors to judge the prospect or profitability of a company. Nonetheless, the practicality of such requirement is still to be seen. The three competent authorities may have different standards with regard to approval procedures. Given that biotech products are inherently new and generally innovative, it is not unlikely that different authorities may form different opinions on the same product. As such, there could be conflicting information in the market about a product and it might create confusion among the investors and turbulence in the market.

2. ***Safety of biotech products***

   Biotech is defined as the application of science and technology to produce commercial products with a medical or other biological application under Chapter 18A.01 of the Listing Rules. This means that biotech products are almost invariably applied to humans for biological purposes, and anything relating to health safety of humans must be subject to the highest standard. While the "Approved Products" requirements under Chapter 18A may provide a certain level of protection, there could still be safety risks associated with a new product. Biotech products pose their unique safety risks to humans. Under the current regime, biotech listing applicants must disclose all material safety data relating to its core products, including any serious adverse events, but it is unclear what constitutes adequate safety data and serious adverse events. Moreover, it is also hardly known to the public yet what basic fitness standard for intake of bio-products, if any, will be required or applied in the vetting process. Safety tests applied by a foreign authority might not be completely reliable, for instance due to demographic variations of customers, or the fact that a competent authority has not yet focused on rigorous product safety testing at the earlier stages of approval. As a responsible exchange, SEHK as a frontline regulator should require and vet adequate safety tests results before approving the listing of companies with clinically ready products. Moreover, there should be comprehensive disclosure of proper safety

safeguards by reference to robust guidelines or regulatory requirements for biotech companies intending to list in Hong Kong.

3. *Industry implications and ramifications*

Unlike other areas, biotech is not yet a well-established and long existing field or industry in the market. There are innovative types of applications for biotech and the state of research and direction of development can be unstable or even volatile. Rule 18A.04(4) of the Listing Rules stipulates that a description of Approved Products (as defined in Chapter 18A) and the length of unexpired patent protection period and details of current and expected market competitors have to be disclosed. While this provides some insight to the prospect of the product, the wider picture could remain in the mist. It is therefore important that listing applicants should disclose the general environment and conditions in the field or market in relation to their biotech products in sufficient detail. In other words, they should depict in an "enhanced" industry overview section of the prospectus of their respective industries and state, among others, statistically supported information about the industry implications and ramifications relevant to the listing applicant, applications of their products, core competitiveness of their companies and the rationale behind expected acceptability of their products in the market. Furthermore, given the uniqueness of biotech products, appropriate expert reports regarding the relevant biotech fields should be disclosed in specific cases. An expert report prepared by professionals with the requisite expertise in judging the future market reception for the products, comparison with other relevant products, prospects of R&D variables and current position of the biotech firm in the market may bring necessary information to the investing public and provide better investor protection.

4. *"Cornerstone endorsement"*

It is stated in Rule 18A.03 of the Listing Rules that an applicant which has applied for listing under Chapter 18A must demonstrate to SEHK satisfaction that it is both eligible and suitable for listing as a biotech company. It has been continuously reiterated in SEHK's publications that the exchange intends to put a standard on biotech listing applicants by introducing the suitability requirement that a biotech listing applicant must have previously received meaningful investment from at least one "sophisticated investor" at least 6 months before the proposed listing. SEHK has certain discretion in determining the adequacy of "meaningful investment" of any such "sophisticated investors". In SEHK's Consultation Conclusions - A Listing Regime For Companies From Emerging And Innovative Sectors, examples of "sophisticated investors" were provided, including:

(i) a dedicated healthcare or biotech fund or an established fund with a division/department that specializes or focuses on investments in the biopharmaceutical sector;

(ii) a major pharmaceutical or healthcare company;

(iii) a venture capital fund of a major pharmaceutical or healthcare company; and

(iv) an investor, investment fund or financial institution with minimum assets under management of HK$1 billion.

Such explanations are useful in shedding light on the regime adopted by SEHK; however, as emphasized by the Exchange, what constitutes a "sophisticated investor" will always be dependent upon a range of factors. The original purpose of this requirement is to demonstrate certain financial market acceptance of the listing applicant to the investing public; in other words, the spirit is having a sophisticated professional investor who has the resources or biotech expertise to evaluate the prospect of the biotech company to act as an "endorser" of the company. However, thinking deeper, this approach could in particular cases be futile because of, for instance, two reasons: firstly, potential lack of clarity of the required expertise of such sophisticated investor; and, secondly and perhaps more importantly, adequacy of requirements regarding the relevant team members of the sophisticated investor, its evaluation methodologies and its financial or other assessment process. In this sense, even if a substantial investor does finance a biotech listing project, it may not by itself be sufficient to provide meaningful assurance, if any, to the investing public of the stability, prospect and profitability of a certain company. More is needed for the disclosure with a higher level of transparency with respect to how such sophisticated investors' express or implied "endorsement" of the listing would be meaningful to the investing public. For instance, a systemic investor review report signed by such sophisticated investor should be disclosed in the listing prospectus (with the original available for public inspection and registered at the Companies Registry). In such review report, the sophisticated investor can set out, among other matters, its qualifications and expertise, the reasons for making the investment, on what bases and assumptions its evaluation on the company was made, the core statistics that it relied on, any data supporting its forecast in relation to the future profitability of the company and any foreseeable risks of the investment (or an appropriate negative statement). This would provide more useful information in achieving the purpose of having such sophisticated investor endorsement to the market; it could be financially unhealthy to the market in the long run if the investing public are allowed to somewhat "blindly" rely on merely the lead of such "sophisticated investors". With relevant information available, investors are better equipped to make their own analysis and form their own view towards whether to invest in certain biotech companies.

5. ***Systemic collaboration between professionals***

In the traditional listing regime of Hong Kong, certain expert opinions are required to be disclosed in the prospectus of the listing applicants. One example is the reporting accountants' report. Under the new sponsor regime which came into force in 2013, a stricter

duty has been put on sponsors in relation to listing due diligence. For a listing application under Chapter 18A, a new form of systemic collaboration between the professionals involved in the listing process is called for, in view of the nature of such listing application. For example, the professionals' due diligence work should put specific emphases relevant to the specific types of biotech products concerned, with meaningful cross-checks so that no material aspects would slip between the cracks. In some cases, certain expert reports, such as an industry-specific consultant's report, may also be required, to which investors may have reference as part of the basis of judgment in relation to the prospects and profitability of the company. Sometimes, if not publicly disclosed, the involvement of certain consultants and the obtaining of their views could back up the sponsor's and other professionals' due diligence. One can envisage that, for biotech listings under Chapter 18A, relevant verification by industry experts would be necessary to alleviate the otherwise unduly heavy burden of responsibilities put on the shoulders of the usual professionals. Hong Kong need to carefully strike a balance between the facilitation of listing of pre-revenue biotech companies and the long term integrity of Hong Kong's financial markets.

## Conclusions

While the newly introduced Chapter 18A of the Listing Rules is certainly a ground breaking and welcome change to the market and it can be seen that SEHK has done a lot of work in developing a sound verification and approval regime, such regime requires particular care and efforts upon implementation. Issues relating to the practicalities of the listing process need to be properly addressed to give credence to the new regime, calling for the introduction of a new collaborative system in which professionals and regulators would play more significant roles in ensuring its success.

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