

23rd March, 2018

Corporate and Investor Communications Department Hong Kong Exchanges and Clearing Limited 12/F, One International Finance Centre 1 Harbour View Street Central Hong Kong

<u>Re: Consultation Paper of a listing regime for companies from emerging and</u> <u>innovative sectors dated February 2018</u>

welcome the changes proposed by the captioned consultation paper because innovative and high growth issuers on The Stock Exchange of Hong Kong Limited ("SEHK"), a subsidiary of Hong Kong Exchanges and Clearing Limited ("HKEX") will help build the cornerstone of the financial ecosystem to foster the growth of emerging and innovative sectors in Hong Kong.

In response to the captioned consultation paper released by the HKEX, refer to Attachment 1 on the commentary on the biotech chapter composed by

We would recommend HKEX to continue to collaborate with **a struct** to drive the growth of biotech and emerging and innovative sectors in Hong Kong. We recommend HKEX to share with **a struct** the contact information of biotech companies seeking IPO so that **a struct** can approach them to introduce policy, focus and support for research and development in Hong Kong and in **a struct**. Also, we would recommend HKEX to continue to join force with **a struct** to promote to potential Biotech companies to set up research and development labs in **a struct**. The services provided in **a struct** may be positioned as a support for companies on the road to IPO in Hong Kong.

In addition, we welcome the proposed changes made for the new WVR chapter and secondary listing rules. Although innovative and technology startups and small to medium enterprises in Hong Kong may not directly benefit immediately from the proposed changes, they will benefit indirectly from having large innovative and technology companies list on HKEX as primary or secondary offerings. We believe

that this helps build a financial ecosystem in Hong Kong (including research houses, investment banks, accounting, legal and financial advisory firms) that support the growth of innovative and technology startups and small to medium enterprises. In addition, we anticipate that the large innovative and technology companies based in Hong Kong help grow the innovative and technology startup community in Hong Kong by creating business demands, research and development needs and investment opportunities in startups.

Please kindly note that we do not wish our name to be disclosed to the members of the public.

Please let me know if you have any questions.



Regards,

<u>Attachment 1: Commentary on Consultation Paper - A Listing Regime for</u> <u>Companies from emerging and innovative sectors</u>

Background

In response to the Consultation Paper released by the

are filing the following commentary to the HKEX. This commentary addresses specifically the issues identified for biotech company pre revenue IPO listing guidelines outlined in the new Biotech Chapter draft.

Biotech Companies

The primary objective of the pre revenue IPO listing for biotech companies was to promote the number of companies to be listed in HKEX, and that this technology sector was identified based on foreign listing records. It was assumed that association with the "regulated product" track, could provide some de-risk mechanism to protect the investors, the market and the reputation of HKEX, since there is no other routine finance-based venue that may offer additional evaluation/assessment/approval information.

A) Suitability to list

1) HKEX recognizes the FDA, CFDA and EMA as "Competent Authorities" (chapter 2, para 76, executive summary, para 9) and may seek SFC for consent if there were additional relevant national or supranational authorities. An example is that the Japan regulatory authority allows n=1 clinical trial and accepts such data for approving stem cell based therapy, which is NOT available in US, Europe or China currently. If there were such Japanese company who meets all of the presumed requirements set by HKEX, the decision to accept the Japanese regulatory authority's decision into the assessment criterion in this particular case, clearly will reside with SFC, but proper advice should be sought from HK regulatory authority, HK Dept of Health (HKDH) or some other designated professional body.

This also brings forth another topic, which is the recognition of the FDA, CFDA and EMA authorities presumably at the same professional level with regard to medicine approval. Currently, HKDH requires prior approvals by **two advanced countries** before HKDH would approve a new medicine for local use/registration, and likely even for clinical trials. Currently as a practice, HKDH does NOT recognize CFDA as one of the advanced countries for local registration/approval purposes. HKEX may need to clarify with HKDH if such wording and recognition were appropriate to avoid confusion even though the clause in para 69 may address the issue.

2) HKEX would demand a biotech company to have a core product beyond the concept stage (para 8) and that it should have intellectual property covered by having patents etc.

While passing ph1 clinical trial is definitely meeting a human safety milestone, in the context of pharmaceutical development, it may have just surpassed 10-30% of the entire clinical trial hurdle, and subsequent failure rate is still high. Understanding that the pre revenue IPO scheme is to facilitate biotech company fund raising to surpass these hurdles, it is acceptable to stick with this threshold. However, the associated preclinical data must be included in the assessment. In addition, the clinical plan for the disease indication to be pursued in ph 2/3 has to be available to justify for the clinical relevance along with a commercial analysis of the intended disease indication[s]. Together, these analyses may provide a more complete panel for assessing an applicant company's activities. Such data should also be monitored as the company progresses and making public announcements. The content of the publicity materials should accurately reflect the scientific findings and interpretations.

While issued patents are always helpful, patent applications may be equally relevant, and would need to be disclosed in confidence. The recent patent dispute between U Berkeley and MIT on genome editing exemplifies the importance in understanding the competition and intellectual property infringement versus ownership. Further, as long as the company has a relevant "license" to use a particular patented technology, that should be an acceptable case as claiming to have the freedom to operate on such technology. It is also common practice to license from academic institutions or pharmaceutical companies to pursue development of a core product. The term "licensed IP" may be included in para 8e.

Currently, there is no requirement for any company to be listed in HKEX to demonstrate any R&D activities in HK, the consideration is purely driven by market or finance interest. While this approach clearly has its merits, it also limits the benefits to HK that these listing companies could have brought forth. HK biotech industry



could have benefit even more, if the to be listed companies were required to set up some R&D in HK **BEFORE** listing or that preference could be given to such companies for listing? The setting up of R&D activities in HK justifies the requirements for a strong R&D and management team of the company, and provides a venue for monitoring or assessing its progress subsequently. This may also partially de-risk for item B below.

B) Expected Market Capitalization

The HKEX proposes a minimum market capitalization of HK\$1.5Billion (para 10) which is reasonable. It is however worth considering an additional sub-item, assetbased-valuation on the company core product that may better reflect the core competency of the company's products and technology. This is because the asset of a Biotech Company varies depending on its clinical application, market size and pricing, be it a diagnostic test or a novel biological drug candidate. Such sub-item analysis may reduce "shell company" risks. It is critical for the first wave of pre revenue IPO listing companies to have strong scientific credentials and technological uniqueness at an international and global level. The value could simply be raised to HK\$2 Billion, and combining with point 2 above, could provide a de-risking mechanisms for enrolling 'shell companies' into the scheme.

C) Enhanced Disclosure Requirements

3) para 11 describes a list of disclosures required from biotech companies.

While all of the items listed are fair, there is an issue with "Confidentiality", that will be a concern versus public offering, assessment and monitoring. This is because it may be insufficient to just provide statements on the development phases, but actually prominent relevant data (para 11a). While granted patents are fully public knowledge, patent applications may not be, and should be classified as confidential materials (para 11g). It is not just for convincing the HKEX, but also serving to protect the company interest, same applies to para 12.

Para 11h stipulates the disclosure of RnD experience of management which is encouraging. It may be further qualified that it should be RnD experience relevant to the core product or its development. This management team, especially the scientific team, has to be disclosed and kept in continuity as much as possible. Changes to Chief Scientific /Technology / Medical Officer positions should be filed with HKEX and the announcements be made public. These personnel are critical factors affecting the successful development of core product and could affect share prices and investment



appetites. In addition, a sound and credible scientific advisory board is equally welcome.

D) Material Change of Business and Delisting Process (para 15)

The recent case of UBS offers confidence to the public regarding the transparency of HKEX and its credibility on a clean and fair listing system. While most of the finance "fraud" could have been identified and dealt with by HKEX, similar system ought to be applicable to the pre revenue IPO biotech companies. In lieu of a revenue (or significant revenue), the highest risk from these companies is data fraud, another is the pursuit of unethical or unapproved activities (may be additional activities and not violating the described core activities during application to HKEX for IPO). These, depending on the seriousness, may trigger fairly significant measures from HKEX including delisting. Monitoring of such activities and data assessment is another hurdle for HKEX.

Recommendations

To address some of the issues listed above, it may be pertinent to set up a separate **vetting committee**, for assessing the technology and scientific potential of the core product of an applicant company. This mandatory vetting committee will be operated by a third party body who can comply with confidentiality while recommending their assessment on the applicant to HKEX. The vetting committee is expected to serve as a gatekeeper to safeguard the quality of the applicant biotech company and integrity of the core product based on professional and technical assessments complementary to that conducted by HKEX. Note the final decisions such as granting approval and cancellation for listing lie with HKEX.



A. Infrastructure

The operating structure of the vetting committee is illustrated as two available options below:



Fig. 1





B. Membership criteria and duties

According to Fig. 1, members of the committee will be solicited to review each individual company according to their expertise. For example, if the incoming company falls under the pharmaceutical area, the appropriate academic specialist, clinical specialist, industry specialist will be someone with extensive knowledge and experience in the sector for drug discovery, clinical trials operation, regulatory system and so on. In terms of capacity, more than one person may be appointed to each category, should a second opinion is required for assessment. The duties of the members would mainly involve, but not limited to, evaluating the suitability of the biotech companies for listing in accordance to the criteria as laid out in 'Suitability to list' and the recommendations above.

These committee members must declare any conflict of interest with the applicant company. Members should also have strict legal liability to inhibit insider trading.

C. Terms and condition of membership

Members should be solicited accordingly on a case by case basis, and compensated according to the level of professional and technical services rendered. The Chair of the committee can either be a representative derived from HKEX or appointed by HKEX on a 2-3 years contract based term. In examining applications for listing under the new biotech chapter, the membership of the vetting committee should also be stringently scrutinized and can involve international experts. As members are entrusted with the disclosure of confidential information of the companies, should any confidential information be disclosed to third parties not involved with the assessment, and jeopardize the integrity of the committee, the corresponding member will have his or her membership revoked. Other scenarios that would also result in termination of membership may include participation in insider trading or situations where the member is affiliated with any "transfer of benefits" such that the assessment is biased. In cases that may result in the termination of membership, HKEX would have the final decision.

D. Workflow

In terms of workflow, the vetting committee may act as an independent advisory board or consultation body to the HKEX, from which mandatory recommendations would be provided to the HKEX on the incoming early stage biotech companies. This would act as the first and foremost gate to screen the



companies. With reference to Fig. 1 and Fig.2, two options are proposed for HKEX's consideration:

Option 1 (Fig. 1)

Applicants will submit applications to HKEX as the first gate to 'general admission', where HKEX can filter the applications based on the general listing criteria and revert the case to the vetting committee to solicit recommendations based on assessment on the technical and business aspects of the company. Then the committee will go through their evaluation process and feedback their assessment report to HKEX.

Option 2 (Fig. 2)

Applications will be submitted directly to the vetting committee, and the committee will provide their assessment reports to HKEX for their consideration. The advantage of Option 2 is to alleviate the burden of vetting workload from HKEX.

With consideration to mitigate the heavy liability thrusted upon the committee, it is advised that the committee should operate behind the scenes, in order to minimize tension and pressure from the public.

E. Suggested Mode of Operation

It is proposed to devise a governance and compensation structure to (a) form a committee of which its independence is maintained, and (b) be able to attract the professionals with the appropriate level of expertise in the subject matter to provide the required advice to HKEX.

F. Importance of successful listing of first batch of biotech companies

We believe that the successful listing and post-listing secondary trading of the first batch of biotech companies are critical to the long-term success of the biotech chapter in HKEX, because they set the expectation of the company standards and shape the investors' confidence and reputation of the biotech chapter in HKEX. It is proposed that the first batch of successful applicants should possess the following qualities in addition to the basic requirements: (a) having an international presence, (b) reasonably reputed and well known internationally, (c) sound research and development team as well as management team, and (d) uniqueness of technology.