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By email (response@hkex.com.hk)
Corporate and Investor Communications Department
Hong Kong Exchanges and Clearing Limited
12/F, One International Finance Centre
1 Harbour View Street
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Dear Sirs

Re: Emerging and Innovative Companies CP

We refer to the Consultation Paper (A Listing Regime for Companies from Emerging and Innovative Sectors) published in February 2018, and attach our comments thereon for your reference.

If you have any questions on the attached, please feel free to contact Brad Shu using contact information above.

Yours sincerely,

Brad Shu

Beijing DHH Law Firm Shanghai Office

COMMENTS ON THE LISTING REGIME FOR COMPANIES FROM EMERGING AND INNOVATIVE SECTORS

1. **Paragraph 18(e) of Executive Summary:** Eternal Validation: the applicant must have previously received meaningful third party investment (being more than just a token investment) from at least one Sophisticated Investor (which must remain at IPO). Such investors will be required to retain an aggregate 50% of their investment at the time of listing for a period of at least six months post-IPO (subject to exceptions for de minimis investments by specific investors provided that the main investors are in compliance).

   DEFINITIONS – "**Sophisticated Investor**" – "An investor that the Exchange considers to be sophisticated by reference to factors such as net assets or assets under management, relevant investment experience, and the investor's knowledge and expertise in the relevant field."

   Our comments: We suggest the Amendment to the Listing Rules (the "Amendment") clarify the eligibility requirements for Sophisticated Investor. In practice, almost every Bio-tech Company which has completed Phase 1 clinical trials should have received investments from various investors including investment fund, listed company and even individual investor. However, investment funds vary in the size of net assets or assets under management, because Bio-tech Companies in early stage often do not select investors by their size of net assets or assets under management.

   If the Amendment did not specify the specific requirements for a Sophisticated Investor to make an investment in a Bio-tech Company which is eligible for listing on Hong Kong Stock Exchange (the "HKEX"), it would be very hard for sponsors, lawyers and other intermediary institutions to determine whether the Bio-tech Company is eligible for listing on the HKEX in terms of the eligibility of the Sophisticated Investor. So we suggest that the Amendment clearly specify the eligible requirements for a Sophisticated Investor to make an investment in a Bio-tech Company which is eligible for listing on the HKEX. For example, the Sophisticated Investor shall have assets of RMB 2 hundred million or more under management, and the senior managers of the Sophisticated Investor shall have at least 3 years of professional years.

2. **Paragraph 78 of Executive Summary**: Based on analysis of Biotech listings in other markets and subsequent discussions with market practitioners and the SFC, we propose applicants for listing under the Biotech chapter must have a minimum expected market capitalisation at the time of listing on the Exchange of HK$1.5 billion (see Appendix I, Rule 18A.03(2)).

   Our comments: Since the Bio-tech Companies targeted by the Amendment do not generate profits or revenues, they should not be valued by price-to-earnings ratio or price-to-sales ratio, which are often used for valuing those Bio-tech Companies which have generated profits or revenues. We wonder if

the HKEX will examine and limit the valuation approach used for valuing a Bio-tech Company which has not generated profits or revenues. And we also wonder if the HKEX will designated the specific valuation approach for valuing such Bio-tech Company, or the valuation of such Bio-tech Company will be totally calculated by sponsors through consultations to investors in the marketplace.

3. **Paragraph 75(a)(ii) of Executive Summary:** 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.

   Our comments: It's hard to understand what's meant by "at least one clinical trial". Generally, if a pharmaceutical product is produced based upon the previously approved products, relevant drug administration (such as CFDA) requires that such pharmaceutical product shall undergo some pharmacokinetics research and at least one hundred controlled randomized tests before its registration. We wonder if the term "at least one clinical trial" means that the applicant needs to involve one patient in clinical trial or to complete only one controlled randomized test. We suggest this Paragraph further clarify the meaning of "at one least clinical trial" so that sponsors, lawyers and other intermediary institutions may determine whether the applicant is suitable for listing.

4. **Paragraph 75(b)(ii) of Executive Summary**: 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.

   Our comments: Similar to the case of a pharmaceutical product based on previously approved products, it's also hard to understand what's meant by "at least one clinical trial" in this Paragraph. We wonder if the term "at least one clinical trial" means that the applicant needs to involve one patient in clinical trial or to complete only one PK/PD test. We also suggest this Paragraph further clarify the meaning of "at one least clinical trial" so that sponsors, lawyers and other intermediary institutions may determine whether the applicant is suitable for listing.

5. **Paragraph 75(c)(ii) of Executive Summary:** 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).

   Our comments: It's also hard to understand what's meant by "at least one clinical trial" in this Paragraph. We wonder if the term "at least one clinical trial" means that the applicant needs to involve one patient in clinical trial or to complete only one clinical test. The clinical trial relating to medical

device is different from that relating to pharmaceutical product or biological product. We also suggest this Paragraph further clarify the meaning of “at one least clinical trial” so that sponsors, lawyers and other intermediary institutions may determine whether the applicant is suitable for listing.