

**From:** [REDACTED]  
**Sent:** 19 March 2018 15:37  
**To:** response  
**Subject:** comments on the draft of consultation paper

Dear HKEX,

We seriously review the consultant paper and think that it is really great to innovation of Biotech. However, if the criteria is very low, we can see that the future market will be a mess and investors will lose their confidence

So we provide some comments as below for your reference,

- 1), The definition of " proof of concept ", we think it might be the product which has safety data and preliminary efficacy data in human.
- 2), The core product should have a big market if it is successful.
- 3), The product should be innovative including product with patent as well as technology with know-how, which should be acknowledged by most of people.
- 4), The company should be the top 3 player in the sub-industry.
- 5), The core product should have human data which shows that it is safe and has preliminary efficacy.
- 6), The core product should classified into "first in class"/"me-better"/"me-too", which can be easy to tell the product's innovation and risk.
- 7), The company should disclosure the mechanism/target, the key R&D person for the core product, any information communicated with CFDA/FDA.
- 8), Suggest that HKEX recognise the FDA, the CFDA as Competent Authorities since the EMA has such as comparable low criteria, especially for medical device's CE marker. Moreover, the EMA doesn't have a big influence on the marketing performance of the product.

We take those proposals into your consideration for the booming market and healthy industry in the future.

It is for your reference. Best wishes with B-market.

Best,

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