BioLingus GmbH

Draft comments/questions on the HKEX Consultation Paper for emerging and innovative companies

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To :

Hong Kong Exchanges and Clearing Limited
Corporate and Investor Communications Department
12/F, One International Finance Centre
1 Harbour View Street
Central
Hong Kong
Email : response@hkex.com.hk
Cc : MichaelMTChan@HKEX.COM.HK

From :

BioLingus GmbH
Grossmatt 6
CH-6052 Hergiswil
Switzerland
Attn : Yves Decadt – CEO
[redacted]

Re : Feedback on Consultation Paper

Introduction

The Hong Kong Stock Exchange intends to attract more emerging and innovative companies to its exchange.
For this purpose, in February 2018, the Hong Kong Stock Exchange has released a Consultation Paper which describes the draft guidelines/conditions for companies wishing to list under these new rulings for emerging/innovative companies.

BioLingus GmbH is a Swiss biotech company specializing in oral delivery of peptides and proteins. BioLingus has reviewed the Consultation Paper, and we have the following suggestions for improvement/clarification of the guidelines.

If you would have any questions or comments on our comments, feel free to contact me directly.

Yves Decadt, CEO BioLingus

Comments on the Consultation Paper :

We have mentioned below the paragraphs on which we have comments, and our comments are written in blue italics.

Paragraph 8 (g) , page 8

(g) it must have previously received meaningful third party investment (being more than just a token investment) from at least one Sophisticated Investor at least six months before the date of the proposed listing (which must remain at IPO)[4].

BioLingus :

We suggest to add that in the case the management team are majority owners of the company, and they have been able to fund the company themselves (without external institutional investor), they should demonstrate that they have similar biotech investment experience as investment experts in a biotech institutional investor, such as a venture capital group.

We also suggest that in case the management team in the innovative company is the majority owner and investor (and no third party "Sophisticated Investor" is present), the company should meet the following criteria

- *The technology used by the company shall be patent protected ;*
- *A valuation report on commercial value of the technology compiled by an independent and experienced valuation expert (or expert group) who has compiled no less than 10 similar reports for IPO or commercial transactions shall be submitted. Financial analysis shall include but not be limited to parameters as risk adjusted NPV (Net Present Value), IRR (Internal Rate of Return) shall be included ;*
- *At least one member of the management team shall have proven experience in managing public companies or leading a company to successful IPO.*

Paragraph 9, page 9

9. The Exchange will recognise the FDA, the CFDA and the EMA as Competent Authorities for the purpose of the new Biotech chapter. The Exchange may, at its discretion, recognise other national or supranational authorities as Competent Authorities in individual cases (depending on the nature of the Biotech Product). The Exchange will seek the SFC's consent before making such a recognition.

BioLingus :

We suggest to add explicitly the Canadian and Australian regulatory authorities, as they are quite often used by European and USA based biotech companies.

Paragraph 75, page 24 :

75. With regards to paragraph 74(a) above, the Exchange would consider the following to demonstrate that a Regulated Product has developed beyond the concept stage.

(a) Pharmaceutical (small molecule drugs)

(i) In the case of a Core Product that is a new pharmaceutical (small molecule drug) product, the applicant must demonstrate that it has completed Phase I clinical trials and that the relevant Competent Authority has no objection for it to commence Phase II (or later) clinical trials.

(ii) 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.

BioLingus :
We suggest to add another category of companies, named Drug Delivery Companies :

Drug Delivery Companies should have special statute, more similar to medtech (in some particular cases the drug delivery system may include a medtech device). As most drug delivery companies develop new routes of administration for existing drugs, the risk profile is far lower than new molecules developed by biotech companies. While the latter still have to proof the safety of the drug, the drug delivery company does not have to do that, assuming they work with "marketed" molecules. ***For a Drug Delivery Company, Proof of Concept requirement should be Proof of Technology for the drug delivery technology. At least pre-clinical non-inferiority should be demonstrated and the company should be able to start clinical studies within one year.***

BioLingus :
The following definition of ***Drug Delivery*** *can be added in Definitions :*
Drug delivery *refers to approaches, formulations, technologies, and systems for transporting a pharmaceutical compound in the body. Drug delivery is often approached via a drug's formulation, but it may also involve medical devices or drug-device combination products.*
Examples of drug delivery technology projects :

- *Changing an injectable route of administration into an oral route*
- *Developing a once a day product instead of a twice a day product*
- *Develop an intranasal or intra-dermal product instead of an oral tablet*

In all these examples, the drug substance itself is not changed.