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23 March 2018

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

Contact Person: Wing L. Cheung
Email Address: [redacted]
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Our Reference No.:

Dear Sirs,

Re: Emerging and Innovative Companies CP
Written comments on Chapter 2 (Biotech Companies)

Introduction

1. We refer to the "*LISTING REGIME FOR COMPANIES FROM EMERGING AND INNOVATIVE SECTORS*" Consultation Paper (the "**Consultation Paper**") which was released in February 2018. Unless the context otherwise requires, terms and expressions defined in the Consultation Paper shall have the same meanings herein

2. We have certain clients (the "**Clients**") who are particularly interested in Chapter 2 of the Consultation Paper ("**Chapter 2**"). In anticipation of the new rules coming into effect, they are keen to implement a listing plan under the new rules. Against this background, we are instructed to submit the following written comments for your consideration.

Comments

3. In a nutshell, we are submitting a general comment about the approach adopted for listing of Biotech Companies, as well as a specific comment about the treatment of in-licensed Core Products.

Partners

Gregory F. BURCH 白貴方 Wing L. CHEUNG 張永良 Lorne W. McDOUGALL 麥勞倫 Matthew H. C. WONG 黃漢柱

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General

4. With respect to the general comment, our clients welcome the proposal to allow listing of Biotech Companies that do not meet the Financial Eligibility Tests. As rightly pointed out in the Consultation Paper, in the US Biotech Companies make up a majority of companies seeking a listing in the early stage of the company's development and the development of the company's Biotech Products. The implementation of the current proposals will no doubt further enhance Hong Kong's leading position as an international finance centre. Furthermore, the competitive edge of The Stock Exchange of Hong Kong Limited will also be sharpened among the world's major stock exchanges because the proposals are responsive to the market feedback that many businesses involved in Biotech R&D have legitimate capital markets needs ahead of having a revenue-generating commercial product or service.

Specific

5. Turing to the specific comment, there appears to be a lack of clarity about the treatment of in-licensed Core Products.

6. The relevant part of the Consultation Paper is paragraph 83(e) ("**Paragraph 83(e)**") which reads as follows:

> **"Enhanced Disclosure Requirements**
>
> 83. Biotech Companies applying for a listing on the Exchange under the Biotech chapter will also be required to provide prominent warning statements and enhanced risk disclosures; including disclosures on:
>
> (e) its rights and obligations in respect of any in-licensed Core Products;".

7. This is echoed in the draft amendments to the Listing Rules:

> **"CONTENTS OF LISTING DOCUMENTS FOR BIOTECH COMPANIES**
>
> 18A.04 In addition to the information set out in Appendix 1A, a Biotech Company must disclose in its listing document:—
>
> (2) the details of each Core Product, including:
>
> (i) to the extent that any Core Product is in-licensed, a clear statement of the issuer's material rights and obligations under the applicable licensing agreement;".

8. Given the express reference to "in-licensed Core Products" in Paragraph 83(e), our clients are delighted to note that an in-licensed Core Product can also form the basis of a listing of a Biotech Company. The flexibility provided by this approach will greatly broaden the coverage to include Biotech Companies which conduct R&D on in-licensed Biotech Products in conjunction with other Biotech Products which are self-developed.

9. First of all and in the context of Chapter 2, one must not be skeptical about a Biotech Company that does in-licensing of Biotech Products that have completed Phase I clinical trials. In fact, the core value creation of a drug development project is heavily loaded in the subsequent Phase II and III clinical trials, which focus on clinical trial protocol design and implementation, and require technical competence on areas such as safety dosage calculation, population pharmacokinetic and efficacy end-point analysis. In order to succeed, the licensee must possess the technical knowledge, working experience with the relevant Competent Authorities, and network of collaboration with local hospitals. It should be noted that Chapter 2 is not concerned with a Biotech Product that is close to commercialization, in which case the licensing arrangements can largely be about sales and distribution rights in respect of a "finished product" in the commercial market. Chapter 2 is actually concerned with Biotech Companies that focus and thrive on R&D. Even in the case of a Biotech Product that has completed Phase I (or even Phase II) clinical trials, there remains a lot of solid R&D to be done and the licensing arrangements tend to be complicated to cover matters such as granting the licensee a broad range of exploitation and other rights to the exclusion of not just third parties but also the licensor in the specified territory, collaboration in completing Phase II clinical trials and above, the enabling the licensee to become the named-holder of the drug's registration at CFDA, and etc.

10. According to our Clients, in-licensing has become a very popular trend in the Biotech industry. In particular, many Mainland-based Biotech Companies are keen to in-license Biotech Products so that further R&D, including clinical trials for further Phases and NDA (new drug approval), can be conducted in the Mainland with the engagement of hospitals in the Mainland. This business model is attractive to Mainland-based Biotech Companies for two main reasons:

    a. the in-licensed Biotech Products will complement and provide synergy with the self-developed Biotech Products of the Mainland-based Biotech Company so that a better pipeline of Biotech Products can be built;

    b. the examination and registration of the in-licensed Biotech Product by CFDA can be facilitated since the clinical trials on human subjects are conducted in the Mainland. Given the incredible size and growth potential of the Mainland market, this will greatly upgrade the commercialization potential of the Biotech Products.

    With the recent promulgation of The Measures for the Administration of Lot Release of Biological Products, Order No. 39 of the China Food and Drug Administration (国家食品药品监督管理总局令第39号, 生物制品批签发管理办法), the prevalence and dominance of such business model among Mainland-based Biotech Companies will surely continue.

11. For similar reasons the reverse is also true – many Biotech Companies based outside the Mainland are also keen to out-license Biotech Products to the Mainland. In this connection, the strategic importance of Biotech Companies based in the Mainland is obvious, as they already have established working relationship with hospitals in the Mainland.

12. In light of the aforesaid, it will clearly be absurd to exclude from the ambit of the new rules this popular, thriving and attractive business model favoring Biotech Companies based in the Mainland[1].

13. However, paragraph 74(e) of the Consultation Paper provides as follows:

> "74. The Exchange proposes that a Biotech Company that does not meet any of the three Financial Eligibility Tests could be suitable to list under Chapter 18A if it can demonstrate the following features:
>
> (e) it must have durable patent(s), registered patent(s), patent application(s) and/or intellectual property in relation to its Core Product(s);"

This does not appear to be in line with Paragraph 83(e), as it can be perceived as an obstacle to a listing under the new rules on the basis of an in-licensed Core Product that has been developed by the licensor beyond the concept stage. As pointed out above, the fact that the licensee, i.e. the Mainland-based Biotech Company, does not have the patents in question should not be taken adversely, since the true and ultimate value of the Biotech Product depends on the quality of the further R&D, in respect of which the licensee has a critical role to play.

14. It is respectfully submitted that the draft rules should be amended to clarify and confirm that:

a. a listing application can be made under the new Chapter 18A on the basis of a in-licensed Core Product;

b. more specifically, to the extent that any Core Product is in-licensed, the Exchange will not insist that the issuer must have or own the durable patent(s), registered patent(s), patent application(s) and/or intellectual property in relation to the Core Product, provided that the Exchange is satisfied that the nature and coverage of the issuer's material rights and obligations under the applicable licensing agreement are sufficient for the purpose of a listing; and

c. in respect of deciding whether the nature and coverage of the issuer's material rights and obligations under the applicable licensing agreement are sufficient for the purpose of a listing, the factors that the Exchange will take into account should be set out clearly.

Conclusion

15. To conclude, our Clients welcome the proposal to allowing listing of Biotech Companies that do not meet the Financial Eligibility Tests. However, in relation to in-licensed Core Products, it is respectfully submitted that the current draft rules should be amended along the line as recommended in paragraph 14 herein so as to make clear that a listing application can be made under the new Chapter 18A on the basis of a in-licensed Core Product.

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[1] For further reading, you may like to check the following links:
https://www.bio.org/sites/default/files/files/BCIC6_8.30.12_FINAL.pdf
https://www.pharmaceutical-technology.com/comment/chinas-new-regulations-set-stage-partnerships-acquisitions/

16. Lastly, if the Exchange considers that it is beneficial to meet with representatives of our Clients to better understand the comments herein and/or discuss how best the draft rules could be improved in light of the market trends, please feel free to let us know and we shall be most pleased to make the relevant arrangements.

Yours faithfully,

[redacted]

Locke Lord