MAYER·BROWN JSM

Legal Update
Hong Kong
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Hi Biotech, are you ready? Hong Kong is ready.

As foreshadowed by many in the market, The Stock Exchange of Hong Kong Limited ("**HKSE**") published its consultation conclusion on 24 April 2018 allowing listing of pre-revenue Biotech companies, the listing application for which will be entertained as soon as next week starting 30 April 2018.

We have published a series on this consultation, please refer to our latest Legal Update of 6 March 2018. The present consultation conclusion also addresses weighted voting rights (**WVR**) and the new secondary listing concessionary route, which we will update you separately.

Below is a recap of which Biotech companies are eligible for a listing on HKSE pre-revenue:

BIOTECH	Primarily engaged in the research and development (**R&D**), application and commercialisation of Biotech products, processes or technologies with medical or other biological application	
CORE PRODUCTS	Regulated by a competent authority, such as the US Food and Drug Administration (**FDA**), China Food and Drug Administration (**CFDA**), European Medicines Agency (**EMA**) or others (on case-by-case basis)	
	Pharmaceutical/Biologics: with a pipeline of potential products	
	Medical devices: must be a Class II medical devise or above (under the classification criteria of the relevant Competent Authority)	
R&D	Engaged with the R&D of its core product(s) for a minimum of 12 months prior to listing, and has registered patent(s), patent application(s) and/or intellectual property in relation to its core product(s)	
AT LEAST ONE CORE PRODUCT BEYOND CONCEPT STAGE	Completed Phase I and received no objection from a competent authority to commence Phase II (or later); and subject to human testing	
	Pharmaceutical: new or based on previously approved products	Completed Phase I clinical trial (or trial conducted on human subjects), and the relevant competent authority has no objection for it to commence Phase II (or later) clinical trials
	Biologics: new or biosimilar	Completed Phase I clinical trial (or trial conducted on human subjects), and the relevant competent authority has no objection for it to commence Phase II (or later) clinical trials
	Medical devices (including diagnostics)	Completed at least one clinical trial on human subjects, and the relevant competent authority (or in case of member(s) of the European Commission, an authorised institution) has no objection for it to proceed to further clinical trials or commence sales of the device

MEANINGFUL INVESTMENT FROM AT LEAST ONE SOPHISTICATED INVESTOR AT LEAST SIX MONTHS BEFORE LISTING (WHICH MUST REMAIN AT IPO)	Meaningful investment	≥5% if market cap is between HK$1.5 billion to HK$3 billion
		≥3% if market cap between is HK$3 billion to HK$8 billion
		≥1% if market cap is more than HK$8 billion
	Sophisticated investor	A dedicated healthcare or biotech fund/department of an established fund
		A major pharmaceutical/healthcare company
		A venture capital fund of a major pharmaceutical/ healthcare company
		An investor, fund or financial institution with minimum assets under management of HK$1 billion
MARKET CAPITALISATION	≥ HK$1.5 billion (at the time of listing)	
TRACK RECORD	In its current line of business for at least two financial years prior to listing under substantially the same management	
	Any change in ownership in the 12 months prior to listing application will be reviewed in assessing suitability for listing	
WORKING CAPITAL	At least 125% of the group's costs for at least 12 months from publication of its listing document (after taking into account the listing proceeds)	
	Must substantially consist of (a) general, administrative and operating costs; and (b) R&D costs	
PUBLIC FLOAT	HK$375m worth of the public float ring-fenced, but cornerstone and pre-IPO investor subscriptions can count in the remainder	
INVESTOR PROTECTION MEASURES	No acquisition, disposal or other arrangement that would result in fundamental change to its principal business will be allowed without the HKSE's prior consent	
	Accelerated de-listing process (12 months to re-comply with requirement of maintaining sufficient operations or asset)	
	Prominent warning statements and enhanced risk disclosure	
	Stock marker "B" at the end of stock name	

Given the specialised nature of the biotech sector, the HKSE announced that it is in the process of assembling a panel of industry experts to form a Biotech Advisory Panel to assist HKSE in reviewing listing applications, including prospectus disclosure and assessing the suitability (including sustainability) of the applicants. The Panel is advisory in nature only and members will be consulted (by the HKSE, the Listing Committee and/or the Securities and Futures Commission, as appropriate) on an individual and "as needed" basis.

Contact Us

Our firm has coordinated resources in handling matters concerning the competent authorities. For enquiries related to this Legal Update, please contact the following persons or your usual contact at our firm.

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