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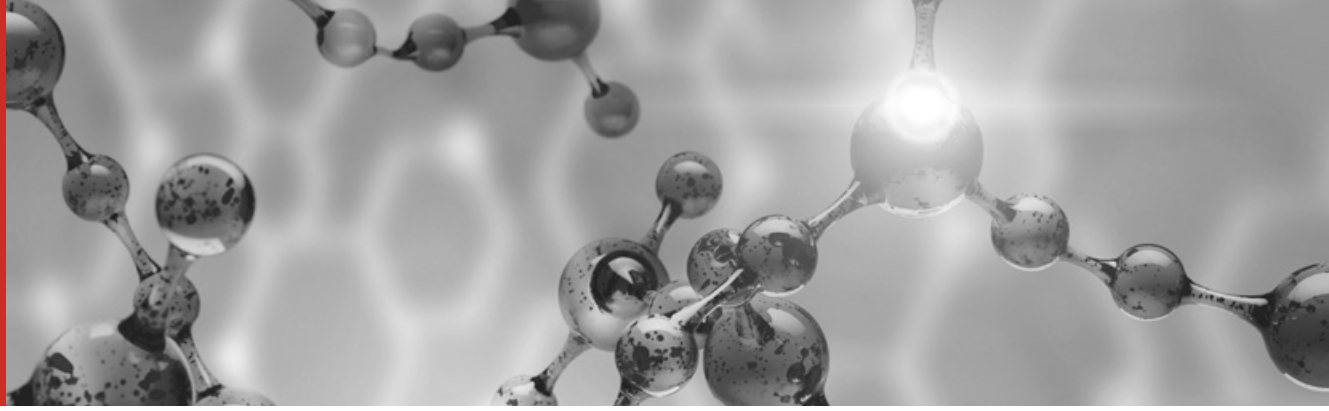
Hong Kong IPO Guide for Biotech Companies



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Introduction

The Hong Kong listing regime was reformed in April 2018 to permit the listing of Biotech Companies (defined below) that do not fulfil the usual financial eligibility tests set out in the Listing Rules. Pre-revenue Biotech Companies may be eligible to list under Chapter 18A of the Listing Rules (Chapter 18A). Biotech Companies listing under Chapter 18A have attracted strong interest from investors, such as the listing of Kintor Pharmaceutical Limited, which Ashurst had recently advised on.

This guide summaries the requirements of Chapter 18A and other guidance issued by the Hong Kong Stock Exchange specifically relating to the listing of Biotech Companies.

This guide covers the following topics:

- **Eligibility and suitability requirements for listing**
- **Disclosure requirements in listing documents**
- **Other matters relevant to listing**
- **Continuing obligations**

For the avoidance of doubt, the guide does not cover the listing of Biotech Companies that can fulfil the financial eligibility requirements set out in Chapter 8 of the Listing Rules, as these Biotech Companies cannot list under Chapter 18A.

Eligibility and suitability requirements for listing

An applicant that applies for listing under Chapter 18A must demonstrate to the Stock Exchange's satisfaction that it is both eligible and suitable for listing as a Biotech Company. In addition to the requirements set out in Chapter 18A, Guidance Letter HKEX-GL92-18[1] provides further detailed guidance regarding suitability for listing.

A "**Biotech Company**" is defined under the Listing Rules as a company that is primarily engaged in the research and development, application and commercialisation of Biotech products, processes or technologies. "**Biotech**" means the application of science and technology to produce commercial products with a medical or other biological application. Biotech Companies generally display the following characteristics:

- they have developed at least **ONE CORE PRODUCT** (defined below) beyond concept stage
- they have **REGISTERED PATENTS** relating to their Core Product(s)
- they are primarily engaged in the research and development of their Core Product(s), and have done so for at least **12 MONTHS** prior to listing
- they have received meaningful **THIRD PARTY INVESTMENT** from at least one sophisticated investor
- their primary reason for listing is to **RAISE FUNDS FOR RESEARCH AND DEVELOPMENT** to bring their Core Product(s) to commercialisation
- for applicants that are engaged in the research and development of **PHARMACEUTICAL** (small molecule drugs) products or **BIOLOGIC** products, they must show that they have a **PIPELINE** of such potential products

However, the above factors are neither exhaustive or binding, as the Stock Exchange will take into consideration all relevant circumstances in determining whether an applicant is suitable for listing. In addition, listing applicants must meet market capitalisation, track record, and working capital requirements.

1 A copy of HKEX-GL92-18 is available at: https://en-rules.hkex.com.hk/sites/default/files/net_file_store/new_rulebooks/g/l/gl9218.pdf

1 CORE PRODUCT(S) BEYOND THE CONCEPT STAGE

Applicants must have developed at least one Core Product beyond the concept stage at the time of the listing application.

A "**Core Product**" is a Biotech product, process or technology that forms the basis of a Biotech Company's listing application under Chapter 18A, which is required by applicable laws or regulation to be evaluated or approved by a Competent Authority (defined below) based on data derived from clinical trials conducted on human subjects before it could be marketed or sold in the market regulated by the relevant Competent Authority.

A "**Competent Authority**" means the US Food and Drug Administration ("**FDA**"), the China Food and Drug Administration (now known as the National Medical Products Administration ("**NMPA**")) or the European Medicines Authority ("**EMA**"). The Stock Exchange may recognise other authorities on a basis[2].

The Stock Exchange would consider a Core Product to have been developed beyond the concept stage if it has met the developmental milestones set out in the table below.

Type of Core Product	Developmental milestones
 • **New pharmaceutical (small molecule drug) product** • **New biologic product**	1. It has completed Phase I clinical trials; and 2. the relevant Competent Authority has no objection to commence Phase II (or later) clinical trials.
 • **Pharmaceutical (small molecule drug) product which is based on previously Approved Products[3]** • **Biosimilar**	1. It has completed at least one clinical trial conducted on human subjects; and 2. the relevant Competent Authority has no objection for it to commence Phase II (or later) clinical trials.

2 Refer to FAQ 036-2018 for factors the Stock Exchange would consider when evaluating other authorities. FAQ 036-2018 is available at: https://en-rules.hkex.com.hk/sites/default/files/net_file_store/new_rulebooks/f/a/FAQ_030_to_044.pdf.

3 An "Approved Product" is a Biotech product, process or technology which has been approved for commercialisation by a Competent Authority.

Type of Core Product	Developmental milestones
 • **Pharmaceutical (small molecule drug) or biologic that is an in-licensed or acquired Core Product**	It has completed at least one clinical trial regulated by the relevant Competent Authority on human subjects since the in-licensing or acquisition. If this has not been completed, the Stock Exchange will assess why this has not been completed and whether substantive research and development work equivalent to the completion of one clinical trial on human subjects has been conducted. Administrative processes will not be considered as substantive research and development work.
 • **Medical devices (including diagnostics)**	1. Categorised as Class II medical device or above under the classification criteria of the relevant Competent Authority; 2. it has completed at least one clinical trial on human subjects; and 3. either the Competent Authority or the Authorised Institution[4] has endorsed or not expressed objection for the applicant to proceed to further clinical trials, or the Competent Authority has no objection for the applicant to commence sales of the device.
 • **Other Biotech products**	The Stock Exchange will consider other Biotech products on a case by case basis to determine whether they are beyond concept stage. If there is no regulatory regime which provides milestones or a framework to assess the developmental progress or clinical relevance of a product, the Stock Exchange may consider matters such as (i) the number, selection process and diversity of the test samples, and data from pre-clinical and clinical trials; (ii) time-frame and hurdles to commercialisation; (iii) whether pre-clinical and clinical results have been published in medical or scientific journals; and (iv) any guidelines published by Competent Authorities. A Biotech Company cannot re-classify their product as "other Biotech products" if it has already been classified as a pharmaceutical, biologics, or medical device by a Competent Authority.

4 An "Authorised Institution" is an institution, body or committee that is authorised or recognised by, or registered with, a Competent Authority or the European Commission for conducting, assessing and supervising clinical trials. The Stock Exchange may recognise another institution, body or committee as an Authorised Institution on a case by case basis.

2 RESEARCH AND DEVELOPMENT

An applicant must have been primarily engaged in research and development for the purpose of developing its Core Product(s) for at least 12 months prior to listing. For example:

- if a Core Product is in-licensed or acquired from third parties, the applicant should demonstrate what research and development they have conducted since the in-licensing or acquisition, such as (i) progressing from pre-clinical to clinical stage; (ii) progressing from one clinical trial phase to the next phase; or (iii) obtaining regulatory approval to market its Core Product(s); and
- if a Biotech Company intends to use a portion of the proceeds from listing to expand the indications of a commercialised Biotech product or launch it in another market, the Stock Exchange expects to see research and development on clinical trials required by a Competent Authority to bring the Core Product(s) for a new indication or commercialisation in a new regulated market.

In addition, a Biotech applicant's primary reason for listing must be to raise funds for research and development to bring its Core Product(s) to commercialisation. In the case of Biotech Companies that produce medical devices which have a short development cycle, the Stock Exchange may take into consideration their business plans and the development stage of their products, so that these companies may use part of the listing proceeds to set up production facilities to manufacture their Core Product(s) and to establish sales and marketing teams to commercialise their Core Product(s).

Applicants that are engaged in the research and development of pharmaceutical (small molecule drugs) products or biologic products must show that they have a pipeline of those potential products.

3 PATENTS

A listing applicant must have registered patent(s), patent application(s) and/or intellectual property in relation to its Core Product(s).

4 MEANINGFUL INVESTMENT FROM SOPHISTICATED INVESTOR

Applicants must have obtained "meaningful investment" from at least one "sophisticated investor" at least six months before the date of the proposed listing (which must remain at the IPO), although this may not be required under certain circumstances in the case of spin-off applications.

The Stock Exchange will assess whether an investment is a "**meaningful investment**" on a case by case basis. They will take into consideration the nature, amount, size of the stake and timing of the investment. The following amount will generally be considered as a meaningful investment:

- for an applicant with a market capitalisation between HK$1.5 billion to HK$3 billion, investment(s) of not less than 5% of the issued share capital of the applicant at the time of listing;
- for an applicant with a market capitalisation between HK$3 billion to HK$8 billion, investment(s) of not less than 3% of the issued share capital of the applicant at the time of listing; and
- for an applicant with a market capitalisation of more than HK$8 billion, investment(s) of not less than 1% of the issued share capital of the applicant at the time of listing.

Likewise, the Stock Exchange will assess whether an investor is a "**sophisticated investor**" on a case by case basis. They will take into consideration the net assets or assets under management, relevant investment experience, and the investor's knowledge and expertise in the relevant field. As an illustration, the following examples will be considered as sophisticated investors:

- a dedicated healthcare or Biotech fund or an established fund with a division that specialises or focuses on investments in the bio-pharmaceutical sector;
- a major pharmaceutical/healthcare company;
- a venture capital fund of a major pharmaceutical/healthcare company; and
- an investor, investment fund or financial institution with minimum assets under management of HK$1 billion.

5 MARKET CAPITALISATION

Applicants must have at least HK$1.5 billion (approximately US$190 million) in market capitalisation at the time of listing.

6 TRACK RECORD

Applicants must have operated their current business for at least two years prior to listing under substantially the same management.

7 WORKING CAPITAL

Applicants must ensure they have sufficient working capital to cover 125% of the group's costs for the next 12 months since the publication of its listing document after taking into account proceeds from its IPO. The applicant's costs must substantially consist of (a) general, administrative and operating costs (including production costs) and (b) costs of research and development.

8 OWNERSHIP CONTINUITY

The Stock Exchange will also review any changes in ownership of a Biotech applicant in the 12 months prior to the date of its listing application in assessing its suitability for listing.

Disclosure requirements in listing documents

A Biotech applicant is required to include the usual information (set out in Appendix 1A of the Listing Rules) in its listing document. In addition, Chapter 18A imposes disclosure requirements specific to Biotech Companies. In April 2020, the Stock Exchange also released Guidance Letter HKEX-GL107-20[5], which provides further guidance on disclosure in listing documents for Biotech Companies.

The following table is a general summary of the additional disclosure requirements that are specific to Biotech Companies. Please note that the table is not an exhaustive list of all applicable disclosure requirements.

Summary section

As Biotech Companies have attracted strong interest from retail investors who do not have biotech or medical knowledge, simple and plain language should be used as far as possible. The summary section should include, among other matters, disclosure of the development timeline of Core Products, and a risk factor that investors may lose of all their investments in the Biotech Company.

Approved Products

It should include a description of any Approved Products, the length of the unexpired patent protection period, and details of current and expected competitors.

Each Core Product

The following matters should be disclosed:

- description of the Core Product;
- relevant regulatory approvals required or obtained;
- material communications with Competent Authorities;
- stage of research and development, including development details by key stages and the indicative timeframe for the product to reach commercialisation;
- material safety data including any serious adverse events;
- immediate market opportunities for each product if it reaches commercialisation, and any potential market opportunities in future;
- details of any patents granted and applied for
- in the case of biologics, disclosure of planned capacity and production related technology details; and
- in the case of in-licenced products, a statement of the applicant's material rights and obligations under the licensing agreement.

5 A copy of HKEX-GL107-20 is available at: https://en-rules.hkex.com.hk/sites/default/files/net_file_store/new_rulebooks/g/l/gl10720.pdf.

Research and development

The following matters should be disclosed:

- details regarding operations in laboratory research and development;
- expertise and experience of key management and technical staff;
- collaborative development and research agreements; and
- legal claims or proceedings that may influence its research and development.

Competitive landscape and market

The following matters should be covered:

- disclose the competitive landscape of its Core Products and other key pipeline products to be commercialised in targeted markets, including
  (i) pipeline products from competitors targeting the same indication and their development stages,
  (ii) the name, price and reimbursement coverage of any such products, and
  (iii) any expiration dates of key patents from competing products;
- disclose material information on the relevant addressable market of Core Products and other key pipeline products rather than the overall market; and
- compare the applicant's products and direct competing products in areas such as technologies, indications, and targeting market.

Communication with Competent Authorities

If the relevant Competent Authority (e.g. NMPA) adopts a one-time umbrella approval procedure, disclosure should be made of any material concerns of objections regarding any completed or ongoing clinical trials. A negative statement should be made if there has been no such communication. For FDA and EMA, all meaningful communication should be disclosed.

Commercialised Core Products

If a Core Product has been commercialised in a specific market for a specified indication, and the applicant wishes to expand the indications or launch it in another market using the proceeds from listing, it should disclose:

(a) a breakdown of the funds used to support research and development, and
(b) their importance of advancing the Core Product.

Pipeline products

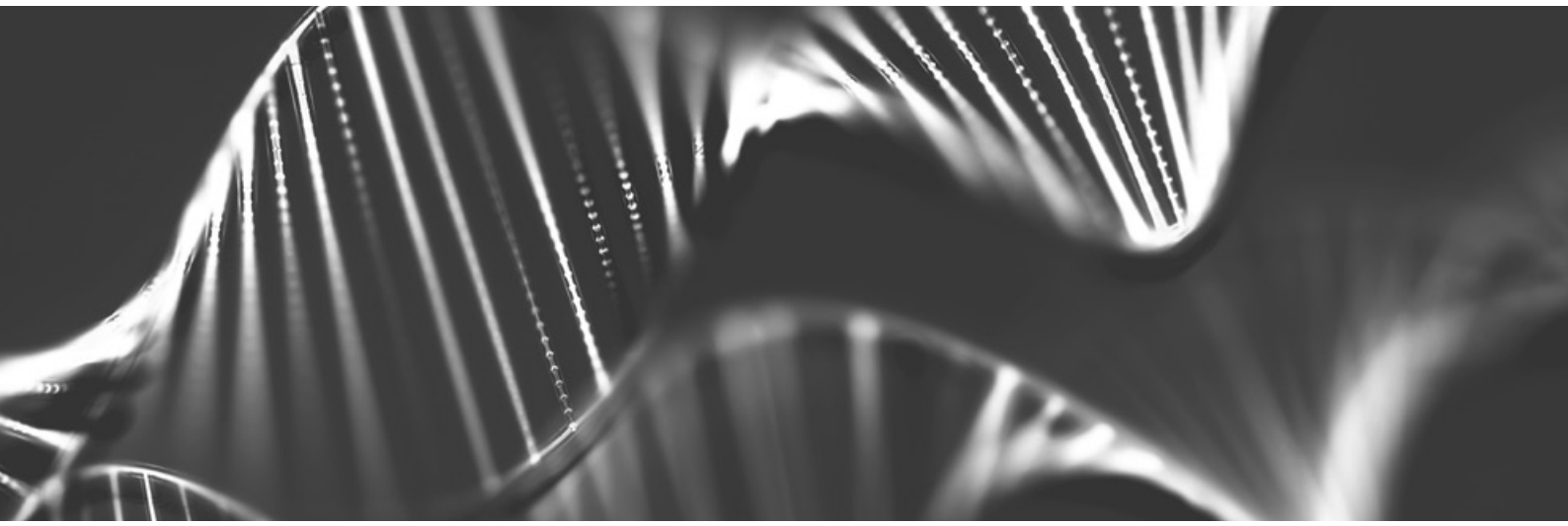
The following matters should be covered:

- specify the origins (i.e. in-licensing or internally-developed) and the jurisdiction rights regarding the Biotech products;
- highlight any pipeline products that will be prioritised for development by the company because of its strategic or commercial importance to the company, or that the company would allocate a large portion of listing proceeds to it even if it has not been developed beyond the concept stage;
- provide a balanced disclosure of material information on relevant studies for each pipeline product;
- for products at a very early preclinical stage, if meaningful preclinical research data is not available or if the data is scientifically sensitive, the Biotech Company should consider excluding it from the listing document; and
- disclose associated risk factors on the inherent uncertainties on pipeline products.

Core Products and advanced pipeline candidates categorised and regulated as orphan medicines and/or innovative therapies

The following matters should be disclosed:

- the basis for drug candidates to qualify in a particular regulatory pathway, any exemptions granted by Competent Authorities regarding regulatory processes and the advantages for drug products admitted, reviewed and potentially approved under such designation;
- the commercialisation plan for the drug product to enter a primary market and other markets, including timing of the next regulatory milestones, and key differences between the primary market and other markets; and
- the calibre and experience of the participants in a collaboration, material terms and conditions of the collaboration, and the owners of intellectual property rights, patent and sub-licensing rights.



Management and key staff

The following matters should be disclosed:

- relevant experience of directors and senior management in the research and development, manufacturing and commercialisation of Biotech products;
- material terms of service agreements between the listing applicant and its key management and technical staff; and
- any measures to retain key management and technical staff, and safeguards in place in the event such key individuals leave the company.

Principal investigators

If the principal investigator who is in charge of or is supervising a Biotech Company's clinical trials has other roles in the company, disclosure should be made of the principal investigator's specific functions in the Biotech Company, compensation, and whether such compensation may impair the integrity of the clinical trials of the Biotech Company.

Risks and dependencies

The following matters should be disclosed:

- potential risks in clinical trials;
- risks relating to the approval process for Core Product(s); and
- extent to which its business is dependent on key individuals in the company and the impact of their departure on its business and operations.

Burn rate

The following matters should be disclosed:

- the period of time, with the basis for it, that the applicant can maintain its viability with its existing cash balance with and without the IPO proceeds; and
- when the applicant plans to raise its next round of financing based on its burn rate.

Valuation

It should disclose the valuation for each round of pre-IPO investments and explain material changes in valuation for each round by reference to key development of the products, business milestones, and competitive advantage over its peers.

Sophisticated investors

It should disclose material information regarding its sophisticated investors, such as the fund's background and its track record in relevant Biotech or healthcare industries.

Other matters relevant to listing

Subscription of shares by existing shareholders

Existing shareholders of a Biotech Company are permitted to participate in its IPO provided that the Biotech Company complies with the public float requirement i.e. at least 25% of the Biotech Company's shares must at all times be held by the public. In addition, at the time of its listing, shares with a market capitalisation of at least HK$375 million must be held by the public.

Shares held by cornerstone investors, and shares subscribed by existing shareholders at the time of the Biotech Company's listing, do not count towards the public float[6].

If an existing shareholder in a Biotech Company holds less than 10% of its shares, it may subscribe for shares in its IPO either as a cornerstone investor or as a placee.

- If the existing shareholder subscribes as a cornerstone investor, the applicant and its sponsor must confirm that (i) no preference was given to the existing shareholder other than the preferential treatment of assured entitlement at the IPO price and (ii) the terms must be substantially similar to the terms given to other cornerstone investors.
- If the existing shareholder subscribes as a placee, the applicant and its sponsor must confirm that no preference in allocation was given to the existing shareholder.

If an existing shareholder in a Biotech Company holds 10% or more of its shares, it may subscribe for shares in the IPO as a cornerstone investor.

6 The Stock Exchange will not regard any core connected person of the issuer as a member of "the public" or shares held by him as being "in public hands". Also, the Stock Exchange will not recognise as a member of "the public" (i) any person whose acquisition of securities has been financed directly or indirectly by a core connected person; (ii) any person who is accustomed to take instructions from a core connected person in relation to the acquisition, disposal, voting or other disposition of securities of the issuer registered in his name or otherwise held by him. See Listing Rules 8.24.

An existing shareholder with a contractual anti-dilution right may exercise its right and subscribe for shares in the IPO of the Biotech Company in accordance with the following requirements set out in HKEX-GL43-12[7]:

(i) the allocation is necessary to give effect to the pre-existing contractual rights of the existing shareholder;

(ii) the listing document and the allotment results announcement fully disclose the pre-existing contractual entitlement of the existing shareholder contained in the relevant investor rights agreement and the number of shares to be subscribed by the existing shareholder; and

(iii) the shares will be subscribed for at the IPO offer price.

Clawback mechanism

If a Biotech Company wishes to propose any changes to the minimum public subscription requirement under Practice Note 18 to the Listing Rules in an IPO, they must provide strong reasons for doing so. The Stock Exchange will consider any such request on a case by case basis.

7 A copy of HKEX-GL43-12 is available at: https://en-rules.hkex.com.hk/sites/default/files/net_file_store/new_rulebooks/g/l/gl4312.pdf.

Continuing obligations

Biotech Companies are subject to continuing obligations that are generally applicable to all Hong Kong listed companies. In addition, they are subject to the following additional continuing obligations that are specific to Biotech Companies.

DISCLOSURE IN INTERIM AND ANNUAL REPORTS

A Biotech Company must include details of its research and development activities in its interim and annual reports, including the following:

- details of the key stages for each of its Core Products under development to reach commercialisation and the indicative timeframe for the Core Product to reach commercialisation;
- a summary of the costs incurred in its research and development activities; and
- a prominently disclosed warning that a Core Product may not be successfully developed and marketed.

STOCK MARKER

The listed equity securities of a Biotech Company listed under Chapter 18A of the Listing Rules must have a stock short name that ends with the marker "B".

SUFFICIENT OPERATIONS

The Stock Exchange may suspend dealings or cancel the listing of a Biotech Company if it considers that it has failed to carry out a business with a sufficient level of operations or assets of sufficient value to support its operations (i.e. Listing Rule 13.24). The Stock Exchange may give the relevant Biotech Company a period of not more than 12 months to re-comply with Listing Rule 13.24. If the relevant Biotech Company fails to re-comply with Listing Rule 13.24 during this period, the Stock Exchange will cancel its listing.

CALCULATION OF PERCENTAGE RATIOS

As Biotech Companies listed under Chapter 18A are not required to meet the usual financial eligibility tests for listing, the application of the revenue ratio and the profit ratio to transactions that they may propose may not be appropriate in certain circumstances.

The Stock Exchange may exercise its discretion, on a case by case basis, to disregard the revenue ratio and the profit ratio for companies listed under Chapter 18A, and consider other relevant indicators of size, including any industry specific tests. Such Biotech Company must provide alternative tests which it considers appropriate to the Stock Exchange for its consideration.

MATERIAL CHANGES TO BUSINESS

Without the approval of the Stock Exchange, a Biotech Company must not enter into any acquisition, disposal, transaction or arrangement, or a series of acquisitions, disposals, transactions or arrangements, which would result in a fundamental change to its principal business as described in its initial listing document.

DISAPPLICATION OF CERTAIN REQUIREMENTS

A Biotech Company listed under Chapter 18A may apply to the Stock Exchange to disapply the "sufficient operations", "material changes to business" and "stock marker" requirements mentioned above. These companies will need to demonstrate to the Stock Exchange's satisfaction that they are able to meet the requirements of Listing Rule 8.05, which sets out the various financial eligibility tests for listing.

Conclusion

Since the introduction of the new regime for listing pre-revenue Biotech Companies, the Stock Exchange has released practical and detailed guidance for Biotech listings, particularly in relation to suitability for listing and disclosure in listing documents. The Stock Exchange's guidance is expected to improve disclosure in the market and to provide a higher level of protection to investors considering to invest in Biotech Companies.

Ashurst has experience in advising Chapter 18A listings, and has recently advised Kintor Pharmaceutical Limited on its successful listing.

In addition, Ashurst's capital market team has advised numerous healthcare and pharmaceutical companies on their successful listing on the Hong Kong Stock Exchange. For further information, please reach out to your usual contact person at Ashurst or one of the authors of this guide.

Selected Ashurst experience in biotech, healthcare and pharmaceutical sectors are as follows:

KINTOR PHARMACEUTICALS SEHK:9939

A clinical stage new drug developer in China, on its HK$1.8 billion Hong Kong IPO and Rule 144A / Regulation S global offering. Huatai Securities is the sole sponsor.

UMP HEALTHCARE SEHK:0722

One of the leading corporate healthcare providers in Hong Kong, on its HK$380 million Hong Kong IPO and Rule 144A / Regulation S global offering. JPMorgan is the sole sponsor.

LUYE PHARMA SEHK:2186

A Chinese pharmaceutical company with a focus on R&D, manufacturing and sale of innovative medications in central nervous system (CNS), oncology and other therapeutic areas, on its HK$5.9 billion Hong Kong IPO and Rule 144A / Regulation S global offering. UBS, Citigroup Global Finance and CITIC Securities are the joint sponsors.

CHINA PIONEER PHARMA SEHK:1345

One of the largest comprehensive marketing, promotion and channel management service providers of imported pharmaceutical products and medical devices in China, on its HK$1.4 billion Hong Kong IPO and Rule 144A / Regulation S global offering. Represented UBS as the sole sponsor.

CHINA MEDICAL SYSTEM SEHK:0867

A leading Chinese pharmaceutical company, on its HK$1 billion Hong Kong IPO and Rule 144A / Regulation S global offering. UBS is the sole sponsor.

LANSEN PHARMACEUTICAL SEHK:0503

A specialty pharmaceutical group engaged in the development, production and sales of specialty pharmaceuticals mainly used in the fields of rheumatology and dermatology in China, on its HK$360 million Hong Kong IPO. Represented Piper Jaffray as the sole sponsor.

TRAUSON HOLDINGS SEHK:0325

A Chinese medical device manufacturer, on its HK$760 million Hong Kong IPO. Represented UBS as the sole sponsor.

PURAPHARM SEHK:1498

A leading Hong Kong-based Chinese medicine manufacturer and the largest supplier of concentrated Chinese medicine granule products in Hong Kong, on its HK$430 million Hong Kong IPO. Represented BOCOM International as the sole sponsor.*

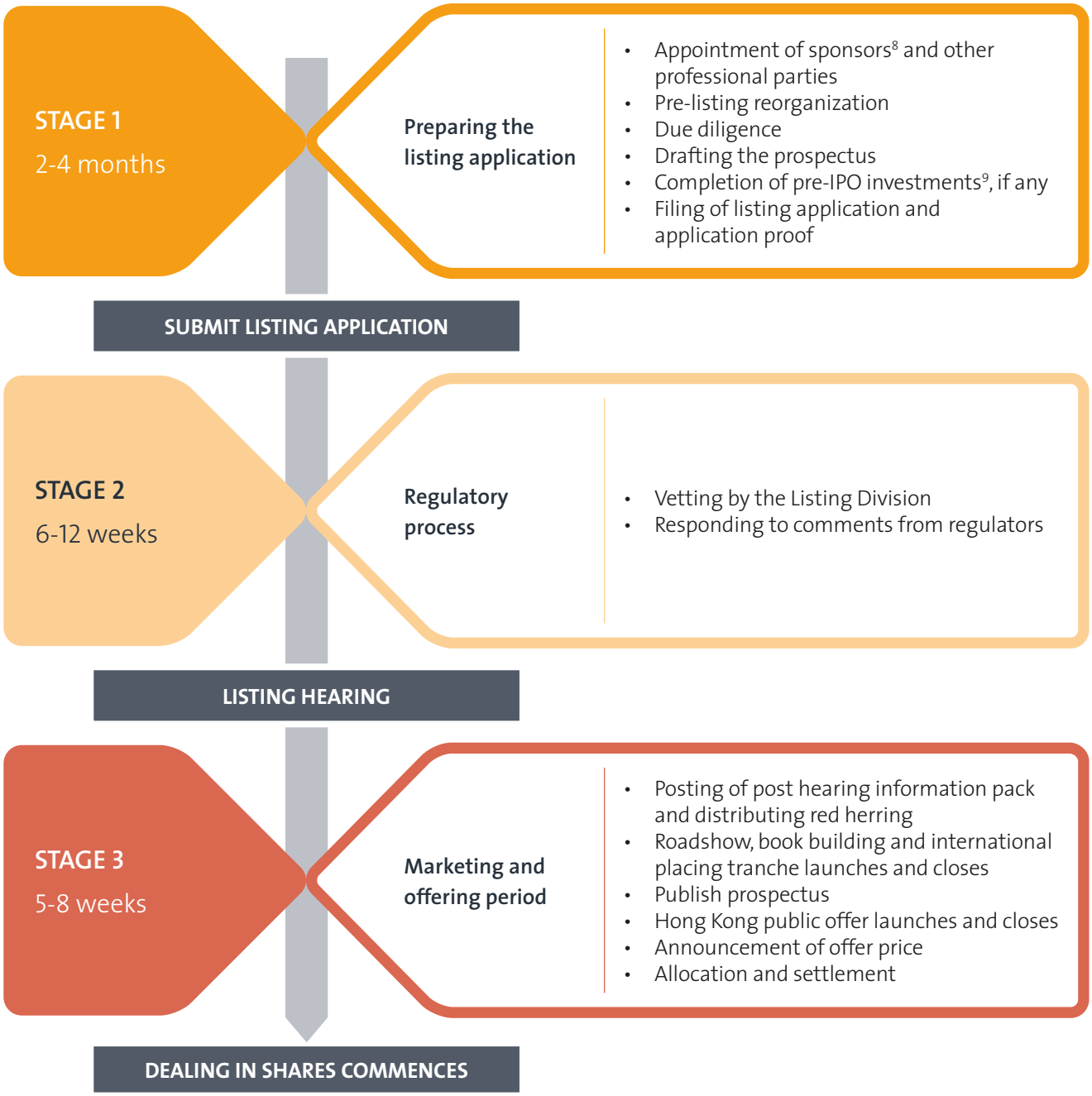
SHANGHAI FOSUN PHARMACEUTICAL SEHK:2196

A leading healthcare company in China on its US$512 million H Share IPO on the Hong Kong Stock Exchange. UBS, CICC, J.P. Morgan and Deutsche Bank are the joint sponsors.*

* Prior to joining Ashurst.

Appendix: Indicative listing timetable

Set out below is an indicative timetable for listings in Hong Kong. The actual duration of the whole IPO process will depend on the complexity of the structure and issues involved.



8 A listing application must not be submitted by or on behalf of a new applicant less than two months from the date of the sponsor's formal appointment. See Listing Rule 3A.02B(1).

9 A listing applicant with a pre-IPO investment made within (i) 28 clear days of the listing application or (ii) after the listing application and before its listing may not list until 120 days from the later of completion of such pre-IPO investment or subsequent divestment. See HKEX-GL43-12, which is available at: https://en-rules.hkex.com.hk/sites/default/files/net_file_store/new_rulebooks/g/l/gl4312.pdf.

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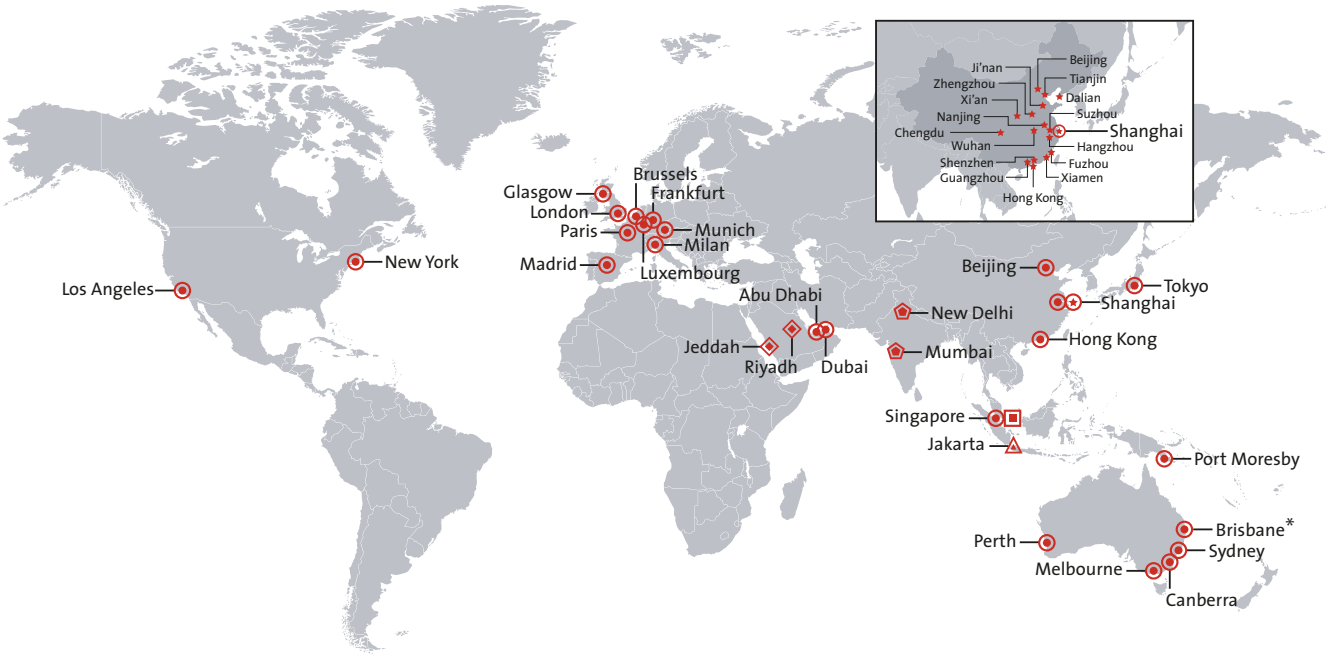

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- Faisal Adnan Baassiri Law Firm (In Association with Ashurst LLP)
- Indian Law Partners (Best Friend Firm with Ashurst)
- ADTLaw LLC (Singapore Formal Law Alliance)
- Oentoeng Suria & Partners (Associated Office with Ashurst)
- Guantao Law Firm (Joint Operation Office)
- Guantao Law Firm

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