Han Kun Newsletter

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Legal Updates

1. Insights into China Biotech's New Approach: Spin-off-NewCo Model[1]

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Background

China's pharmaceutical industry is witnessing a notable surge in "pipeline spin-off projects", a model commonly referred to as the "Spin-off-NewCo" or "SON" model. Within the past two months, we've been advising on nearly ten SON projects. Leading pharmaceutical companies in China are more frequently adopting the SON model to separate parts of their pipelines into new, independent companies. These spin-off projects have garnered considerable interest from multinational industry leaders and international investment institutions, underscoring substantial opportunities for global collaboration.

The SON model is a response of the market to changes in the financing environment and cross-border investment regulatory environment. In the current China and international capital market environment, traditional exit paths for investment in China biopharmaceutical industry have become less clear. Some biopharmaceutical companies, particularly those that achieved high valuations through financings before 2022, are now facing increased financing challenges. Certain sectors, like AI pharmaceuticals and gene therapy, find it difficult to place China and foreign businesses under the same group entity for overseas financing due to risks associated with changes in cross-border investment regulations, foreign investment, and regulatory restrictions. These factors prompt Chinese pharmaceutical companies and investors to seek alternative ways to achieve financing or investment exit, with the SON model offering a solution.

This article tackles key industry concerns by offering an in-depth analysis of the SON model from a practical standpoint. It aims to support pharmaceutical companies and investors in exploring new strategies for global expansion and to serve as a reference point for industry discussions and collaboration.

Overview of the SON model

While the traditional license-out transaction model typically generates revenue through license fees, the SON model introduces a more diversified approach. Unlike the traditional models, the SON model's consideration is not confined to licensing fees; it also includes equity interests and operational control in a newly established autonomous company ("**NewCo**"). This innovative model allows companies and investors to benefit not only from licensing revenues but also from the financial gains of NewCo pursuing exit strategies, including, without limitation, private equity funding, acquisitions, and independent public offerings.

The essence of the SON model lies in creating NewCo around specific pipeline products with promising market potential. This structure provides NewCo with focused core asset and greater operational flexibility in areas such as operations, sales, and capital market activities. For instance, NewCo can

[1] For the Chinese version, please click *《药企出海新热点：管线分拆"SON"模式的实践解读》.*

efficiently attract global partners and more easily license its products to multinational pharmaceutical companies. NewCo is also well-positioned to execute an outright or reverse merger, as well as a De-SPAC transaction overseas as part of its exit strategy. Notably, some pipeline spin-off projects even secure external licensing agreements or complete business sales immediately upon the completion of spin-off.

Particularly when spinning off the pipeline to overseas markets, NewCo can capitalize on comparative advantages offered by cross-border investment regulations, as well as eased restrictions on foreign investments and import-export policies. Moreover, through strategic tax planning, NewCo has the potential to achieve more advantageous tax positions on a global scale.

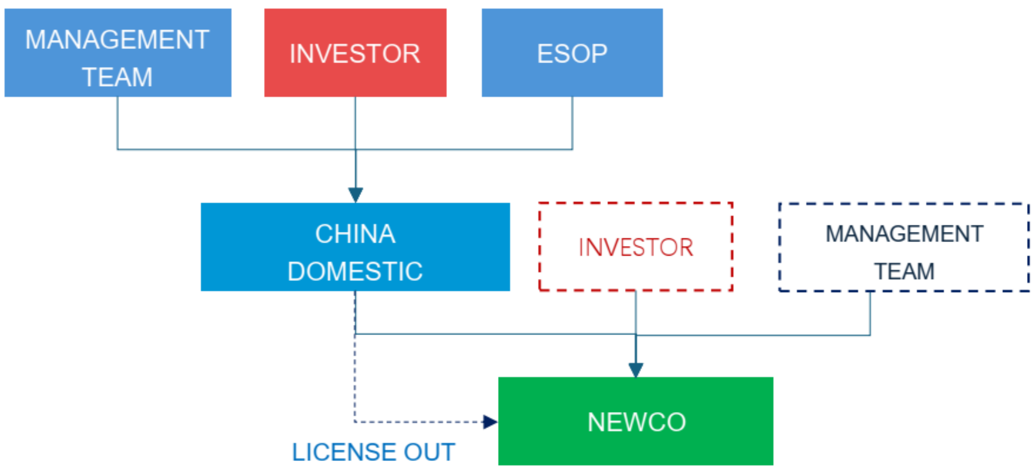
As active participants in the life sciences industry, we have recently had the privilege of assisting numerous clients in executing customized SON projects centered around their innovative pipeline products. While pipeline or business spin-offs in the pharmaceutical sector are not a novel concept, the current wave of industry enthusiasm has brought renewed focus to these strategies. Over the years, we have amassed extensive experience in facilitating pipeline spin-offs aimed at both international expansion and entry into the Chinese market. The successful completion of these projects has provided us with invaluable practical insights and significantly enhanced our expertise with the SON model.

Key points in implementing the SON model: a multifaceted view

I. Shareholding structure: common shareholding structures in the SON model

The common structures in the SON model include controlling or minority shareholding structure, and parallel structure. Based on practical experience from multiple projects, we briefly introduce these structures and the considerations for choosing them as below:

1. Controlling or minority shareholding structure

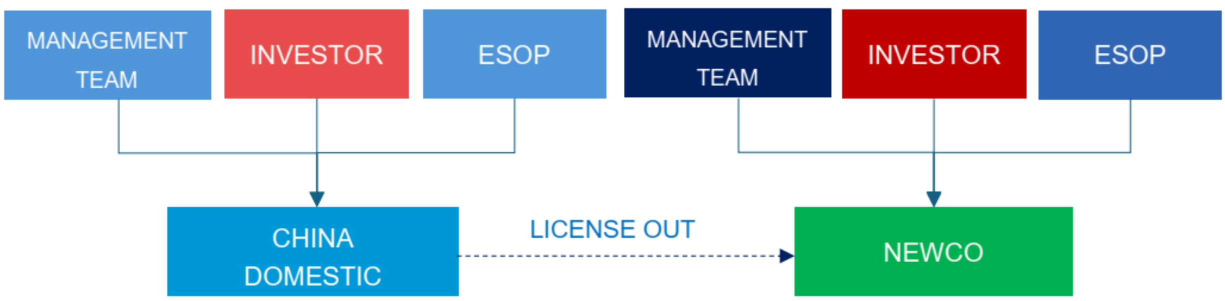


In a controlling or minority shareholding structure, the China domestic company will directly or indirectly hold shares in NewCo. Shareholders of the China domestic company (usually including the management team, investors and employee stock incentive platforms) can indirectly hold NewCo shares through the China domestic company or rollover of part of their shares in the China domestic company proportionally down to NewCo level to hold the shares of NewCo directly.

When deciding whether to take the controlling shareholding structure or the minority shareholding structure, the following factors are usually considered:

- The possibility of the China domestic company's listing and the possibility of the NewCo's independent spin-off listing;
- Whether NewCo will be in competition with the China domestic company, which may affect the China domestic company's listing;
- Whether NewCo already has expectations or potential opportunities for license-out or sale: if so, shareholders of the China domestic company may prefer to roll over most of their shares in the China domestic company proportionally down to NewCo level to hold the shares of NewCo directly, forming a minority shareholding structure, facilitating shareholders to directly gain from NewCo's license-out or sale transactions;
- Whether NewCo has expectations or potential opportunities for new external financing: if so, new external investors may require NewCo to operate independently and request the China domestic company to reduce its shareholding in NewCo so that the China domestic company will not control NewCo. According to our practical experience, if there is some business synergy between the China domestic company and NewCo, and the China domestic company adds value or resources to NewCo's operations, new external investors of NewCo often require that the China domestic company's shareholding in NewCo not be too low to enhance the interest connection between the two companies.

2. Parallel structure



In a parallel structure, the China domestic company does not directly or indirectly hold shares in NewCo. In some pipeline spin-off projects with a parallel structure, all or part of the shareholders of the China domestic company will hold shares in NewCo in proportion to their relative shareholding in the China domestic company. In some other cases, the management team and investors investing in NewCo will hold shares in NewCo, without mirroring the shareholding structure of the China domestic company.

When deciding whether to take the controlling or minority shareholding structure or the parallel structure, the following factors are usually considered:

- Whether the business being spun off overseas has clear independent listing expectations or expectations of obtaining a suitable independent financing valuation;

- Whether the China domestic company is prohibited or unsuitable to hold shares in NewCo from the perspective of business operations, and investment review and compliance regulation;
- The synergy and relevance between the China domestic company and NewCo's business, in light of which whether investors have demands for the China domestic company to hold shares in NewCo.

II. Licensing transactions

Changes in pipeline-related rights remain a critical focus of licensing transactions under the SON model. Therefore, all arrangements involving pipeline rights must be meticulously organized. For example, the following terms need to be clearly defined and appropriately arranged: upstream intellectual property (IP) related to the spin-off pipeline, contractual arrangements with downstream vendors, financial terms, and the rights and obligations to be undertaken by NewCo.

1. Upstream IP

In the SON model, the pipeline being spun off may involve licensing from an upstream licensor. In such cases, it is crucial to pay close attention to the specifics of the upstream licensing and authorization. Additionally, consider how changes in IP rights during the spin-off might affect the responsibilities of all parties involved. These responsibilities could include obtaining necessary approvals, sending required notifications, and making payments for upstream license fees.

In practice, professionals must meticulously review all agreements related to upstream IP, including master agreements, supplementary agreements, and other collaboration agreements. It is crucial to thoroughly consider the existing arrangements of upstream IP when drafting the collaboration agreement for spin-off transactions.

2. Financial terms

In the SON model, the spin-off party typically acquires certain equity interests in NewCo. If NewCo has multiple shareholders, it is essential for all shareholders to agree on the distribution of proceeds generated from future potential mergers and acquisitions (M&A) and financing transactions. In practice, the consideration provided by future third parties often comes in various forms, such as upfront fees and milestone payments. Additionally, the spin-off party may request to obtain royalties from the licensed product through multiple layers, which differs from the typical forms of consideration in standard M&A and financing transactions.

To ensure smooth sailing for the spin-off project, it's essential to nail down the financial terms upfront. This involves defining the scope of NewCo's future proceeds to be shared and crafting a clear distribution mechanism — whether by specific indications, fields, or types of proceeds. Additionally, setting royalty rates, whether fixed or progressive, and harmonizing financial terms before and after M&A transactions are key steps.

3. Contractual allocation of rights and obligations

In addition to sorting out upstream IP, attention must also be given to the relationship between the spin-off party and downstream vendors. If the spin-off party had commissioned CRO/CDMO/CMO and other partners for product R&D and/or manufacturing, these partnerships need to be redefined in new contracts during the spin-off project.

Moreover, the rights and obligations that NewCo needs to undertake under the SON model also need to be considered in new contractual relationships, including but not limited to the application and execution obligations with respect to the relevant clinical trials and marketing authorizations.

III. Taxation and other aspects

Tax planning is also an indispensable part of the SON projects. For instance, in internal spin-off projects (i.e., projects conducted within the corporate group), or in the internal spin-off phase of external projects (i.e., projects conducted with entities outside the corporate group), it is crucial to focus on the pricing of internal spin-off assets (which may require asset evaluation procedures), intra-group financial arrangements, and the optimization of tax structures.

Given the variations in tax systems across different jurisdictions, careful tax planning in cross-border transactions — such as selecting the optimal location for establishing NewCo — may significantly reduce tax costs. Additionally, the unique asset profiles (such as IP status), profitability stages, and future business plans of different companies necessitate tailored solutions based on specific circumstances. These require the assistance of professionals familiar with tax, legal, and industry expertise to optimize the project process and ensure the smooth establishment and implementation of the arrangements.

Analysis and prospects

As Chinese pharmaceutical companies increasingly expand their global presence, the concept of “In China for Global” is being embraced by a growing number of companies. In this context, Chinese pharmaceutical companies are actively exploring new strategies to advance the international development of their innovative drug pipelines with huge market potential.

We have observed that an increasing number of Chinese pharmaceutical companies are consulting and exploring SON transactions, with many already initiating related projects. This international transaction model is more complex than standard licensing deals, as it encompasses not only product and technology licensing but also cross-border financing, transaction structure design, tax planning, and other critical aspects. Successfully navigating these complexities requires a comprehensive professional team for thorough consideration and meticulous planning. We recommend that companies stay attuned to these trends, assess the market potential and international competitiveness of their pipelines, and pursue broader market development through innovative international strategies.

2. NFRA to Unify Compliance Regulation for Financial Institutions

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Background

On 16 August 2024, the National Financial Regulatory Administration (**NFRA**) issued a consultation draft of the *Measures for Compliance Management of Financial Institutions* (*金融机构合规管理办法*) (**Draft Measures**). The public comment period is open until 17 September 2024.

Developing unified compliance management measures for relevant financial institutions can be traced back to the 2022 legislative agenda put forth by the China Banking and Insurance Regulatory Commission (**CBIRC**). This objective remained a key focus in the legislative work plans for both 2023 and 2024, even after CBIRC transitioned to NFRA. Following this, the Draft Measures have been released for public comments, which comprise five chapters: general provisions, compliance management responsibilities, compliance management assurance, supervision and liability, and supplementary provisions.

Insights

The Draft Measures summarize and reiterate compliance practices developed over the years for Covered Financial Institutions (defined below). We believe most Covered Financial Institutions have generally implemented the compliance management mechanisms which the Draft Measures stipulate.

The Draft Measures further underscore the significance of the chief compliance officer (**CCO**) and compliance officer roles and systematically delineate the responsibilities of the compliance department. The Draft Measures signal that the financial regulatory authority will further strengthen compliance supervision over Covered Financial Institutions going forward.

Highlights of the Draft Measures

The Draft Measures provide the following:

I. Covered Financial Institutions

Article 2 of the Draft Compliance Measure outlines the scope of covered financial institutions (**Covered Financial Institutions**), which includes banking, insurance, and other institutions under the supervision of NFRA.

The Draft Measures are not intended to apply to institutions regulated by the China Securities Regulatory Commission (**CSRC**), such as fund management companies, securities firms, and futures companies. In the future, CSRC may introduce similar compliance measures for the financial institutions it regulates.

II. Compliance rules

Article 3 of the Draft Measures outlines the rules with which Covered Financial Institutions would have to comply. In addition to the laws, regulations, and administrative normative documents promulgated by regulators, the Draft Measures stipulate that Covered Financial Institutions must also observe industry self-discipline norms and internal regulations.

III. Responsibilities of the board

Article 8 of the Draft Measures provides that the board of directors of Covered Financial Institutions shall appoint the CCO and ultimately oversee and be responsible for compliance management.

IV. Appointment of CCOs and compliance officers

Article 11 of the Draft Measures would require each Covered Financial Institution to appoint a CCO at their head office and designate compliance officers at provincial-level or first-tier branches. The CCO and compliance officers would need to satisfy the qualifications specified in Articles 14 and 15 of the Draft Measures respectively, and not be permitted to assume additional roles that potentially conflict with compliance management. However, these qualification requirements would not apply to the institution's or branch's president or general manager, should they be appointed to concurrently serve as either the CCO or compliance officer.

V. CCO responsibilities

Articles 16 to 23 of the Draft Measures provide for the responsibilities of the CCO role. In summary, the CCO is to be accountable for the comprehensively managing compliance of the Covered Financial Institution and its employees. This includes guiding, supervising, and inspecting operational management and employee performance from a compliance perspective, as well as ensuring the establishment and implementation of the compliance management system. Furthermore, the CCO would be required to prepare regulatory reports, organize compliance reviews, handle major compliance incidents, and promptly report and advocate for corrective actions in the event of significant violations or compliance risks.

VI. Role of the compliance department

Section 3 to Chapter 2 of the Draft Measures establishes the role of the compliance department. According to Section 3, a Covered Financial Institution would generally be required to establish an independent compliance department tasked with offering compliance support, executing compliance reviews, and delivering compliance training. To ensure effective functioning, the compliance department would be required to operate independently of other business departments with potential conflict of duties. Overseas branches would be required to adhere to local regulations and establish local compliance departments. The compliance department would report to the CCO, with branch-level compliance departments reporting to the compliance officer of that branch.

VII. Compliance assurance

Chapter 3 of the Draft Measures provides an assurance mechanism for effective compliance management. Covered Financial Institutions would have to provide sufficient support to the CCO and the compliance department to ensure their independence and access to information. Each Covered Financial Institution would be expected to employ enough compliance staff to uphold these standards and the CCO would have the authority to participate in meetings, review relevant documents, and issue warnings for compliance risks. Furthermore, Covered Financial Institutions would need to establish appropriate assessment and compensation standards for compliance staff to reinforce the overall effectiveness of compliance management. Additionally, the Draft Measures would make it essential to enhance internal compliance training and implement a transparent internal reporting mechanism.

VIII. NFRA supervision

Chapter 4 of the Draft Measures designates NFRA as the authority to be responsible for supervising the compliance management of Covered Financial Institutions. The CCO and other compliance officers could be investigated and subject to severe administrative penalties from NFRA, or even criminal charges, if they violate the Draft Measures, leading to significant compliance violations or risks for the Covered Financial Institution. However, the CCO and other compliance officers would ordinarily not be held personally liable if they were diligent in performing their duties.

IX. Miscellaneous

The Draft Measures are intended to enter into force on 1 March 2025. From this date, the Draft Measures would replace the existing rules[2] and take precedence over the regulations and rules concerning the qualifications and responsibilities of directors, supervisors, and managers[3], as outlined in Article 65 of the Draft Measures. Covered Financial Institutions would then be granted a one-year transition period from the effective date to comply with the finalized measures.

Our observation

After the Draft Measures are finalized, we suggest the Covered Financial Institutions review and revisit their existing compliance system (including policies, departments, personnel, etc.) against the Draft Measures for a gap analysis and take further actions as required to ensure compliance staff are adequately deployed, compliance department is effectively organized, compliance duties and responsibilities are clearly allocated, and compliance support mechanisms are properly established during the transition period.

Going forward, we recommend that Covered Financial Institutions develop and upgrade their internal compliance training system to provide necessary and high-standard education to all relevant stakeholders to build an enhanced compliance culture.

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[2] Including:《商业银行合规风险管理指引》《保险公司合规管理办法》and《中国保监会关于进一步加强保险公司合规管理工作有关问题的通知》.

[3] Including:《中资商业银行行政许可事项实施办法》《农村中小银行机构行政许可事项实施办法》《外资银行行政许可事项实施办法》《银行业金融机构董事（理事）和高级管理人员任职资格管理办法》《保险公司董事、监事和高级管理人员任职资格管理规定》《非银行金融机构行政许可事项实施办法》and《中国银监会关于银行业金融机构法律顾问工作的指导意见》.

Important Announcement

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