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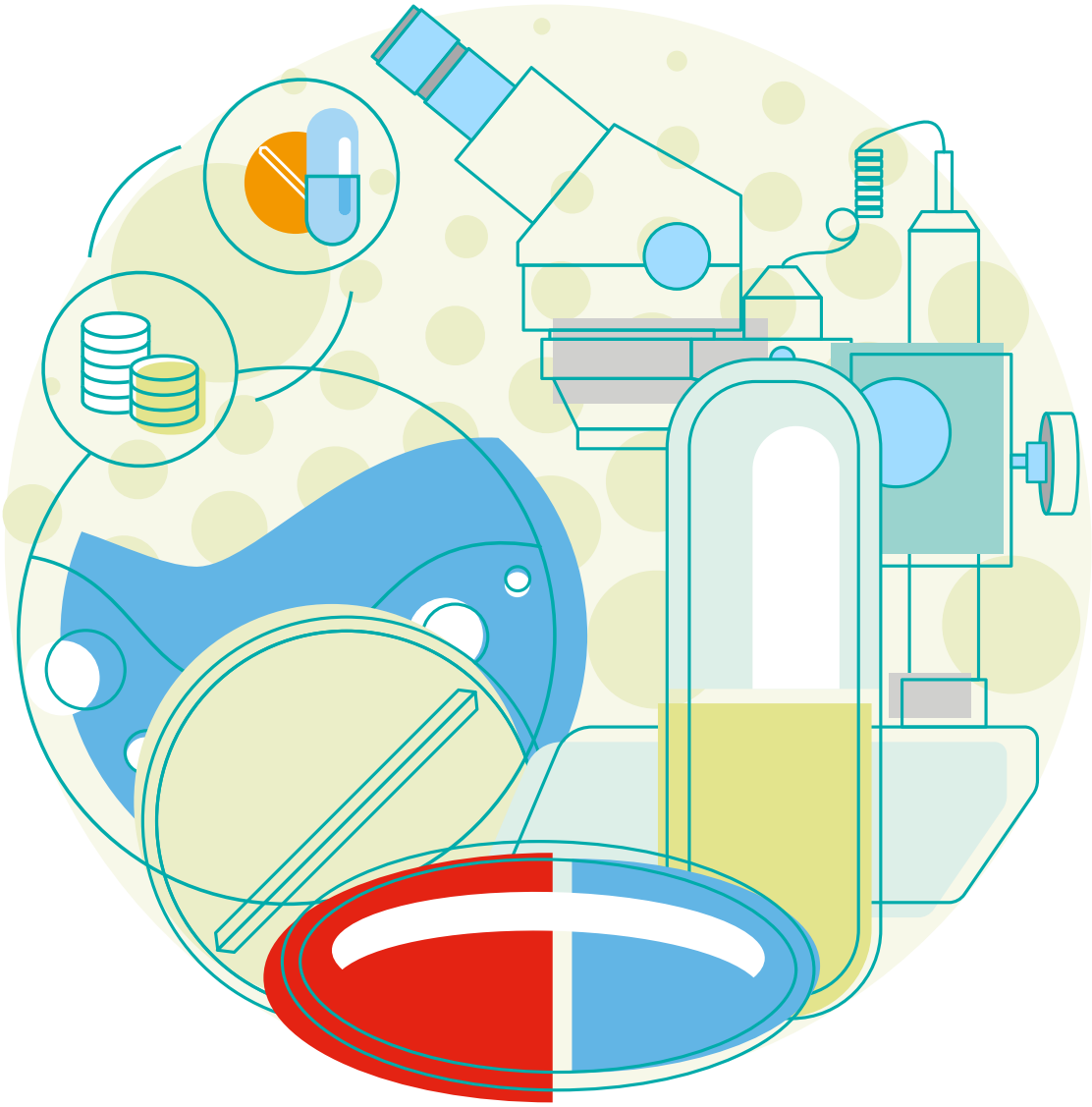

Challenges and Value Creation in China Life Sciences Licensing

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Contents

Abstract

In recent years, medical product (pharmaceutical, medical devices and diagnostics) licensing deals have surged in China, in terms of both deal volume and value. Yet, during the licensing deal life cycle, licensors and licensees face many challenges, making it difficult to realize the strategic objectives of licensing deals.

This paper outlines the practical challenges transaction parties encounter according to Deloitte's observations from projects advising companies to improve their licensing transaction performance. These observations are made through both companies' internal perspectives and external parties' feedbacks on why the transaction fails. To address these challenges, the paper shares some best practices from strategic, operational, and business levels to build and enhance licensing transaction management capabilities, along with an execution roadmap for companies to take immediate actions.

I. Introduction

Lately, the scale of cross-border and domestic licensing deals of medical products in China has been expanding. Licensing deals were active throughout 2021 as demonstrated by the record-breaking deal volume, deal size, and diversity of product across types, therapeutic areas and development stages. According to the 2021 Annual BD Deals Report for China Pharmaceutical Industry released by MyBio Capital, there were 174 publicly reported cross-border drug licensing deals involving Chinese enterprises, in just drug products alone. This included 133 License-in deals and 41 License-out deals. Also, there were a total of 107 licenses between Chinese pharmaceutical enterprises.

It's not surprising to see that the licensing deal has become the most sought-after business development model in China's pharmaceutical industry. On one hand, due to the changes in drug procurement and reimbursement regulatory policies in mainland China, pharmaceutical/ medical device enterprises in China are under significant stress to maintain profitability and good return on investment. Capital market investment in biotech and biopharma has cooled down lately as investors took a more rational view on pipeline/asset quality and commercialization outlook. Many biotech companies are taking a more pragmatic approach to diverse the investment risk or quickly capitalizing on R&D investment through licensing instead of building their own full-scale capabilities covering the entire value chain from R&D to commercialization. Some other biopharma companies are suffering from me-too pipelines and are looking for leveraging commercialization capabilities to reach economy of scale. These intentions were well reflected by the fact that the portion of commercialized products (vs. in pipeline products) in total licensing deals hit a new high in 2021 since 2014. On the other hand, overseas licensors also value this vast market and actively seek to expand their presence in China. China's government has released a series of policies stimulating R&D in recent years, attracting multinational and domestic pharmaceutical/ medical device enterprises to invest in innovation, contributing to an active licensing market.

However, what lies behind the thriving multi-billion-dollar deals is not merely the transaction of money and products. Signing of the deal does not indicate the fulfillment of the goal either. The parties involved often embark on a long and arduous journey to fulfill the contract afterwards. Licensing deals go way beyond just "buying the rights and interests of a product". They require long-term collaboration to diligently fulfill each party's responsibilities from R&D, production, to the commercialization stages. Throughout this journey, the parties involved are often confronted with many challenges in fulfilling a licensing agreement and realizing strategic goals. Therefore, all parties involved in a deal must clarify their business development strategies and transaction purposes, fully assess the capabilities of each party, anticipate and promptly mitigate potential issues and problems that may emerge.

II. Challenges in Contract Fulfillment

In practice, the goal achievement rate in licensing deals is not ideal. For example, a global leading medical technology company that Deloitte once served, had a relatively more mature and comprehensive licensing management process. Yet, among the 40+ licensing deals (including co-development and co-marketing) with over ten partners, less than 50% of the deals met the set strategic goals. As licensing deal history in China is relatively recent, goal achievement rates for Chinese companies remain questionable.

Considering the importance of the topic, Deloitte has surveyed several Chinese pharmaceutical/medical device companies with rich experience in licensing deals over the past decade. The survey results have revealed the various challenges involved in fulfilling the licensing deals as categorized in the following four types:

1 **Lack of clear strategy and cooperation purpose:** Companies sometimes lack a clear product portfolio strategy and opportunistically pursue new products, targets, therapeutic areas, and indications. These types of companies often lack the capability to sustainably or properly fulfill the transaction responsibilities.

2 **Insufficient capabilities or inadequate evaluation of the parties involved:** There are no corresponding departments and personnel to coordinate the tasks related to contract fulfillment from the parties involved. Additionally, the parties involved might not be fully aware of the capability, either of its own or the other party, to fulfill the deals. For instance, the R&D milestone expected by both parties might be affected by the financial status or lack of R&D capacity and sustainability of the partner. Also, the partner may be incapable of undertaking tech transfer or regulatory or compliances infrastructure. These are all plausible cases of unsatisfactory results.

3 Failure to predict possible problems in fulfilling licensing deals:

The licensees may underestimate the difficulties. For instance, there may be difficulty in patient recruitment in practice, thus clinical research cannot be carried out smoothly. The risk of failed tech transfer, lack of accurate judgment on market demand, development and changes of competing products or substitutes, improper coordination of capacity improvement and supply chain management, and underperformance of marketing and sales teams are all among the possible causes of failure. In License-out deals, the licensors may overemphasize the deal price and the payment ability of the licensees, and the amount of the upfront payment. Issues such as failing to understand the target overseas market, overestimating product profitability, and inability to track the progress of contract fulfillment may pose challenges to achieving subsequent sales milestones and sales commissions.

4 Ineffective responses to unforeseen events:

Licensing deals face a long lifecycle of fulfillment. During this period, industry policies such as updates on clinical registration regulations, changes in the medical insurance policy, and adjustments to market access policy may emerge. The companies may fail to predict or respond effectively. Also, the market might change during this period with newly launched competitive products and substitutes or a drop in price. In this case, the value of the product will be seriously undermined before it is launched in the market. Previous profit forecasts may need to be reassessed. There may also be cases when clinical trial results of the product fail to meet expectations, or there's a serious delay in getting the approval to launch the product. Finally, the market development may exceed or fail to meet the expectations after the product is launched, leading to the risk of contract termination by the party whose (potential) interests are damaged.

These challenges encountered by Chinese enterprises are caused by both external policies and market environments, as well as the insufficient management capabilities of all parties involved in the cooperation. In today's fiercely competitive market and increasingly high transaction costs, Chinese enterprises should focus on self-diagnosis and improve their licensing management capabilities systematically.

The challenges in terms of the enterprises themselves mentioned above can be roughly attributed to two reasons – unclear cooperation purpose with inadequate understanding of the capability of both parties, and insufficient capability to predict and cope with the difficulties that emerge in fulfilling licensing deals. To address the former, the parties involved in licensing deals need to better understand themselves as well as their partners and assess the alliance capabilities via various dimensions of evaluation. To address the latter, the parties involved can establish, optimize and reshape the license management process, with the guidance of industry experts. On top of this, they can set up a dedicated department to track the progress, train the employees involved, communicate early in the negotiation process to address possible risks, and formulate a detailed execution roadmap for the whole process. The goal is to maximize the potential value of licensing deals.

III. Alliance capabilities

(I) Scope

As the parties involved in licensing deals have different obligations in different types of deals, the scope of alliance capabilities that they should possess to fulfill the deals also vary. Taking a common license deal type in China as an example, the following figure shows a general implementation process of a licensing deal:

1 If a licensed product has been/is about to be marketed in China, produced by the licensor in China, and its licensing scope covers commercialization right in China – the alliance capabilities of the licensee will be reflected in its sound financial status and domestic capabilities related to market access, marketing, and sales. Meanwhile, the alliance capabilities of the licensor shall be reflected via its capabilities in product registration, production, and supply chain management.

2 If the licensed product is in Phase II or Phase III of a clinical trial abroad, produced by an overseas CMO engaged by the licensor, planned to participate in multi-regional clinical trial (MRCT) initiated by the parties involved, and its licensing scope covers product R&D and commercialization right in China – the alliance capabilities of the licensee will be reflected in its capacities of clinical research, product registration, supply chain management, market access, as well as marketing and sales in China. Meanwhile, the alliance capabilities of the licensor will be revealed by its abilities in clinical research, product registration, production, and supply chain management overseas.

3 For early stage licensing assets/targets in a licensing agreement covering scope including global R&D, production, and commercialization – the alliance capabilities of the licensee shall be mainly reflected by its abilities in clinical research, product registration, supply chain management, market access, marketing, and sales in China. In this case, the alliance capabilities of the licensor will only involve its R&D capability related to the product.

(II) Observations and recommendations

Deloitte has evaluated the alliance capabilities of several pharmaceutical/medical device companies undergoing licensing deals. The evaluations cover two aspects – maturity assessments (internal) and strength of partnership (external). With years of experience in advising companies to improve their licensing management capabilities in the life sciences industry, we have summarized typical problems that exist in fulfilling licensing deals via an internal view of companies and an external review of partners. To address and solve these problems, targeted recommendations have also been proposed. The observations and recommendations are summarized as follows:

1. Observations and recommendations from internal maturity assessments

	Observation	Recommendation
1	**The deal value is not clearly understood or articulated to align with corporate strategy** • The value of the deal is not articulated in a consistent manner and does not align with the company's corporate strategy and business priorities, making it difficult for functions to prioritize their efforts. **Case 1:** When a company is committed to exploring its own advantages, consolidating or even expanding its business scale in a specific therapeutic field, it should choose licensed products in the relevant field. For instance, Company A, engaged in drug R&D, production, and sales in the field of diabetes, should introduce upgraded product or technology in this field. By doing so, it can fully leverage its existing advantages in clinical research and market, and such a choice is also consistent with the company's strategic positioning and business priorities. **Case 2:** If Company B hopes to develop new products for ophthalmic treatment while it is engaged in diabetes drugs, it must strategically clarify the purpose of such cooperation. For instance, the indication of the licensed product has a specific synergistic effect with diabetes; there is a promising market prospect in the field of eye diseases, and Company B can gradually establish an R&D/clinical team in ophthalmic treatment with access to medical experts in this field; being licensed the new product will give the company access to a certain technology/intellectual property right of the licensor or specific government resources. Otherwise, the allocation of resources among various departments of the company will be chaotic, delayed, or even insufficient.	**Evaluate partnership opportunities using a common strategic framework** A clear company strategy can guide the selection of partners or products for cooperation, the allocation of capital and resources, the degree of control and management in fulfilling the licensing deal, and the position of the licensed product. The company should establish a clear set of guiding principles to avoid losing priorities in the licensing deal. • A licensing deal shall fully align with the company's strategic imperatives to reflect the value of the deal. Each licensing deal should have a clear, specific, and acceptable strategic purpose. • A licensing deal should involve a clear decision-making process, and have a set of value drivers, market models and financial scenarios in place to assess the value of the licensing deal and the level of empowerment by both parties. • The decision-making logic of licensing deal should be approved by all departments involved in the decision-making and execution.

	Observation	Recommendation
2	**The selection of licensed products does not always consider functional implications** • Lack of functional diligence has resulted in sub-optimal deal structures, including terms that: (1) require significant company resources to support the partner; or (2) are inconsistent with company capabilities or commercialization purpose. **Case 1:** Company C is a Chinese medical device distribution company. It has a mature and stable marketing and sales team for NMR apparatus and other large medical devices, and it has performed well. However, it hopes to expand its operating revenue in a short period of time and intends to develop new product lines. Coming across a chance to introduce high-end dental implants and related products from abroad, it has decided to pursue this path. Yet, its existing team has no experience in the sales of such products, and Company C needs a new sales team to engage in this new business. **Case 2:** Company D is a Chinese enterprise with strong R&D capability in oncotherapy products. To develop its overseas markets and obtain more funds, it intends to license the rights of a product, currently in Phase II clinical trial, to pharmaceutical companies in major overseas markets. D is deciding between two licensees. One of them is Company Z, a well-known multinational pharmaceutical company in the field of oncology. Z has excellent R&D and market access capabilities in major overseas markets. But D is concerned that, with Z's rich pipeline of oncology products, Z may not pay enough attention to the licensed product. It is also possible that Company Z may include all kinds of products with the same indication to exclude competitors. In that case, the product value will not be fully reflected. Another choice would be Company Y, a mediocre local pharmaceutical company in the field of oncology. Company Y hopes to make a difference in the field of oncology and intends to further expand the market by introducing new products in this field. As such, it is willing to pay high licensing fees and intends to expand its team to completely manage the R&D and launch of the licensed product. However, Company D feels that there is a significant gap between Company Z and Company Y when it comes to implementation capabilities, so the value of the product might not be fully reflected as well.	**Perform selective functional diligences to validate deal value drivers** • Incorporate the due diligence findings and feedback from all functions (commercial, R&D, operations, etc.) involved before making decisions. • The assessment should include both the market potential of the licensed product (external) and the strengths of both sides to realize the value of the licensed product (internal). Due diligence may not prevent the emergence of all problems in fulfilling the deals. But, having a thorough understanding of the strengths/weaknesses of the company itself (or the partner) and the market environment will allow for more proper judgments on the partnership. If the conditions for licensing deals are not sufficient, due diligence is also conducive to formulating detailed and feasible implementation plans for both parties.
3	**Insufficient consideration is given to how deals will be operationalized (R&D, production, commercialization, etc.), and no one to follow up or assume responsibilities** • Functions are not engaged early enough, typically only after deal closure, which hinders their ability to assess customer and functional impacts and plan for execution. • Lack of responsible function to report key matters such as launching time and profit forecast during the transaction, and usually to be optimistic, resulting in reassessment for a reasonable forecast.	**Conduct impact assessment to inform functional engagement.** • Relevant functions should be engaged to assess resource impacts and timing, informed by the diligence findings. • A detailed resource model should subsequently be incorporated into the financial model and business case. • The licensee should designate a business division to take over the marketing and sales of the licensed product when making decisions. The business division should assess the key matters of the licensed product, such as the R&D and launch schedule and profit forecast. In this case, the responsibilities of all functions can be allocated in a result-oriented approach. • The aforesaid key matters should be included in the performance appraisal of relevant personnel in charge of licensing deal reporting, requiring periodic review and confirmation.

	Observation	Recommendation
4	**Functional resources are not appropriately allocated to execute** • The deal model often does not consider an appropriate level of resourcing or, in cases where it does, does not consistently result in incremental allocation of resources or re-prioritization of existing activities. **Case:** Company E and its partner Company X agreed to introduce a small-molecular chemical drug developed by the latter, and the product will be introduced into China as an imported product. Company X engaged an overseas CMO to produce the licensed product, but Company X lacked the ability to select/manage the CMO (as X is not the main client of the CMO). The CMO is rigid in its production arrangement, so the cycle of capacity adjustment is long. In the third year after Company E was licensed the product, the product was included into China's medical insurance reimbursement list. Foreseeing the rapid increase in market demand, Company E informed Company X of its plan to increase purchases. But Company E was informed that the CMO could not make a sizable adjustment to its capacity as Company E demanded in a short period. As a result, the products couldn't be supplied as planned by Company E, so it's hard for Company E to rapidly boost its sales volume in the short run.	**Obtain resource approval prior to deal signing** • Governance approval from the (s) PAC or an alternative governance committee with appropriate authority should be required prior to deal execution and should include the allocation of necessary resources. • When negotiating on relevant important resources externally, pay special attention to the management of CMO and other third parties. This includes detailed stipulations on the plan adjustment, supply guarantee, and responsibility of default in the licensing or supply agreements. In the case that detailed stipulations cannot be made, communicate thoroughly with parties involved on possible changes or adverse impacts. Fully grasp the situation and ensure information symmetry. • Designate a special division to take over the communication matters and assume corresponding responsibilities.
5	**Ambiguity around accountability for deal success** • Deals are pursued without identification of a single point of accountability for deal success, which has led to misaligned objectives and incentives and unclear roles and responsibilities. **Case:** The fulfilling of a licensing transaction involves various activities, including sub-licensing, clinic trial, data detection, clinical/commercial drug supply, purchase/sales, quality, pharmacovigilance, product registration, market entry, marketing, medical affairs, medical information, warehousing and transportation, sub-package, commissioned production, and insurance, etc. While these are responsible for different functions with no reporting relationships. Moreover, they need cross-function collaboration from finance, tax, legal, HR, marketing, and government affairs, etc. which is very challenging to coordinate.	**Set up a RACI matrix; identify and empower a business sponsor responsible for deal success** • Establish a management model, specify the RACI matrix, improve process files through system design, break down the work contents of license transaction, assign different tasks to specific departments, and clarify the exit and entry timetable of departments involved in the process, along with their work content and scope of responsibilities. Ensure the smooth progress of work even with staff turnovers. • In multinational companies with higher alliance capabilities often have a special alliance division set up to track the progress of licensing deals, clarify powers and responsibilities, formulate unified standards, and effectively manage the projects. Research shows that this will increase the success rate of licensing deals by 40% and cut down management costs. Generally, depending on the functions of departments based on the company's current management framework, this division can be set up under the strategy, business development, or the R&D department. The personnel of the allied division should be served as a bridge for internal and external communication, and they are able to guide people in other functions to communicate with the partner. • In certain licensing deals, ultimate accountability should be held by a single senior business sponsor and cascaded throughout the organization to ensure all parties understand their roles and responsibilities and that they are incentivized accordingly. Be aware that alliance partnership established for licensing deals is vital to the company, and the deals concluded in recent years are becoming increasingly complicated. As such, don't rely on a single individual to drive a licensing deal, rather than relevant departments to perform the responsibilities.

	Observation	Recommendation
6	**Lack of unified standard for project management** • Lack of project management departments. • Absence of the management system for periodic review and confirmation.	**Establish a system to manage and track the execution** • A centralized mechanism should be established to provide visibility. • Clarify the appraisal standard for all functions involved when signing the licensing deal. • Refer to the deal management mode of investment institutions to manage licensing deals under a unified standard. This includes periodic review or retrospection of the projects on a monthly or quarterly basis, evaluation of the project implementation status (e.g., red, yellow, and green lights), and intervention in the status of the projects (e.g., level-I, level-II, and level-III responses), etc.

2. Observations and recommendations from external alliance partners

	Observation	Recommendation
1	**Joint strategy and deal vision are not consistently articulated** • The strategic intent and deal vision are typically developed independently by each partner and are not consistently revisited in alliance meetings, leading to a transactional relationship that fails to capture the full potential partnership value. **Case:** The two parties have very different cooperation purposes and are not revisited in alliance meetings. For a certain imported licensed product, Company F, as the licensee, hopes to fully verify the local market potential of the imported product before it transfers and localizes production so that it can guarantee its own interests to the greatest extent. However, Company W, as the licensor, hopes that Company F can transfer the production as soon as possible. If Company F can directly apply for NDA and produce local products, Company W will not need to take responsibility as the holder of the marketing authorization for the imported product.	**Develop a shared vision during negotiation** • The alliance vision should articulate how the partnership supports each party's core strategic objectives. • This shared vision should serve as a north star throughout the alliance's lifecycle and should be used to evaluate if/when operational activities require recalibration.
2	**KPIs do not always clearly support partnership strategy** • Strategic objectives are not clearly translated into KPIs and metrics, other than contractual deal milestones, making it difficult to track progress and articulate success.	**Define a common understanding and framework to track success** • The strategic objectives of the alliance should guide the development of a balanced scorecard in consensus with the alliance partner. • Balance scorecard should be structured to track strategic, financial, operational, commercial, and cultural metrics that underpin the deal vision.
3	**Insufficient operational alignment and visibility hinder execution** • Joint operating protocols often do not exist, and operational processes are largely independent, with limited visibility into the partner's operations, which challenges the ability to seamlessly execute.	**Establish joint operating processes early in the deal design** • A joint end-to-end operating procedure, outlining the activities across partners required to execute the alliance, should be developed prior to deal execution. This should ensure all processes and handovers can be successfully deployed.

	Observation	Recommendation
4	**Resourcing challenges diminish the potential value of alliances** • Significant turnover or capital changes can have a negative impact on the partner's assessment to fulfill the deal. **Case:** The partner lacks R&D capabilities and financial sustainability. For example, in the third year after Company G in China signed a license agreement for a certain product with Company V from Europe, Company V, as the licensor, suffered a serious loss of R&D personnel and its financial situation deteriorated. This resulted in a lack of follow-up R&D, and it is possible that Company V may terminate the R&D of indications that were partly licensed. The multi-regional clinical trials, as planned by both parties when the licensed product was introduced, were also postponed. This change has disrupted Company G's plan to carry out relevant clinical trial and subsequent business development in China. Mostly, the licensor is usually more aggressive in the deal, and they seldom make promises to the licensee when it comes to R&D progress, especially for products in the early R&D stage. Therefore, the licensing agreement neither provides stipulations regarding the relevant time at which the licensor will complete clinical trial on any indication, nor does it provide relevant breach liability. The licensee is thus easily left without help. To break the deadlock, Company G ended up investing in Company V to increase its cash flow and expand the number of clinical trials to be carried out in China among the multi-regional clinical trials. Consequently, the expenditure of Company G for the licensing deal has exceeded the forecast they came up within the decision-making process.	**Maintain resource continuity and executive engagement to the extent possible** • The senior manager responsible for the licensing transaction or any employee acting as an alliance manager should be retained for the duration of the relationship and should be capable of facilitating both strategic and operational discussions. • Understand the counterparty's financial situation and plan through due diligence, to gauge their impact on the operation. Communicate to have a better judgment on whether to cooperate and design deal terms. **Case:** In the due diligence on Company U, the licensor and a listed company, its stock price showed a significant downward trend, reflecting the lack of confidence among investors in its products currently under development. Company U also announced that the fall in share prices, along with other issues, may lead to its delisting. After evaluating its financial statements in recent years and its budget for future product R&D, Company U was found to have poor financing capacity in the past. This also means it has limited working capital for R&D. In addition, as the company faces the risk of delisting due in part to its share prices and net assets, its financing capability will further deteriorate. Without the ability to support subsequent R&D activities, its ability to fulfill contracts is doubtful.
5	**Accountability is not clear and decision making is slow** • Partners are often not able to identify a single point of accountability. • Furthermore, decision-making processes are slow and inefficient, creating a negative perception as a partner. **Case:** During the licensing deal, both parties will usually have a project manager or alliance manager for communication. However, neither the project manager nor the alliance manager is the decision-maker or person in charge of a particular matter in the RACI matrix. With a lower level, they're only able to deliver information internally and act as liaison externally. The partner will thus feel that the responses to their requests are slow, or there is no one responsible for the request. This will adversely affect the cooperation.	**Communicate roles and responsibilities for the partnership and share internal processes to manage partners' expectations** • Roles and responsibilities of alliance teams, including the executive sponsor and others involved in the decision-making processes, should be communicated to the partner. • Streamline decision making where possible, and where this is not possible, share the process and rationale with partners.

It's worth noting that all our observations above have come from companies with industry-leading alliance capabilities. Yet, there are still obvious deficiencies and room for improvement even among these top performers in the industry. As such, pharmaceutical/medical device enterprises should be prudent when it comes to handling licensing deals.

IV. Solutions

(I) Dimensions for improvement

With our observations and recommendations above, we propose that to achieve the strategic objectives of the licensing deal, a company should improve its management capability of the licensing deal at strategic, operational, and business levels. These three dimensions interact with and influence one another:

1 At the strategic level, the company should have a clear development direction and path. There should be a clear positioning of the partners and products in the licensing deal. This means the strategic objective should lead the operation and business of the company. Complete consensus should be reached between the various departments of the company and the external parties involved when it comes to cooperation purposes.

2 At the operational level, the company should formulate regulations on the entire management process of the licensing deal. Adjust the management line, set a dedicated department, articulate/ authorize responsible personnel, enhance the communication efficiency, step up on team training, and reiterate the strategic objectives to guide the development of the business.

3 At the business level, the company should follow a standardized operational process and manage each licensing deal according to the features of the partner and the licensed product, ensuring smooth execution of the licensing deal.

(II) Execution roadmap

In view of the analysis above, we've designed the following roadmap to cover the whole process of fulfilling a licensing deal. Work objectives for all processes have been formed according to key deliverables to help realize a smooth execution of the licensing deal.

	Objectives	Key deliverables
1 Strategic positioning	• Strategic rationale • Partner and product evaluation • Prioritization	• Cooperation strategy map • Strategic imperatives-gaps and accelerators map • Partner financial analysis • Partner tier framework • Cooperation path
2 Searching partner/ product	• Define licensed product • Compliance checks • Product assessment • Deal documents • Internal & external communication strategies	• Deal team structure and assignment • RACI matrix • Compliance checklist • Initial go/no-go criteria • Commercial, legal, technical, and financial evaluation report • Communication plan
3 Due diligence	• Adjust governance structure and deal team • Contact partner(s) • Establish deal process • Due diligence • Compatibility review • Operational model • Negotiation preparation	• NDA, LoI, MoU • Technical and functional evaluation report • Impact assessment • Resourcing model • Proposed alliance governance & operating model
4 Negotiations	• Adjust governance structure and deal team • Negotiate partnership terms • Formulate operating guidelines • Plan internal messaging strategy	• Relevant legal documents • Alliance governance structure and operating model • Milestone plan, BSC, and KPI • Internal & external communication strategies
5 Agreement Execution	• Clarify cooperation model • Adjust deal team • Finalize deal plan	• Relevant legal documents • Tactical plan for alliance • Press release and internal communication
6 Implementation	• Implement licensing deal	• Alliance launch checklist • Alliance team structure • Kick-off deck • BSC • Information sharing process • Crisis management process
7 Management, Monitor & Assessment	• Track deal implementation • Analyze performance and identify corrective measures	• Milestones and financial tracker • Risk reporting • Governance checklist • Health check • Term sheet and contract amendments
8 Termination	• Ensure successful alliance termination	• Termination/ adjustment plan • Learnings review and summary

Please note that, given the varying partners, licensed products and contents, each licensing deal should have a customized execution roadmap. After a full evaluation of the alliance capabilities of the parties involved, the execution roadmap should include a deeper formulation of the work objectives and execution steps alongside the transaction. The key deliverables should be formed accordingly so that the organizational structure and work process will be established, improved, and even reshaped. The roadmap should fully consider how business departments should coordinate with functional departments and should specify significant events as well as risk plans across the board. Finally, the roadmap should be optimized dynamically throughout the entire process of fulfilling the licensing deal.

V. Conclusion

As investors for China biotech and biopharma companies are becoming more rational, the development of new drugs is becoming more expensive. We expect licensing collaborations will maintain as one of the favorable options for many pharmaceutical companies. These licensing options help companies offset their research and development investments and bypass the cumbersome innovation and development process. A prudent partner should be fully aware that signing the licensing agreement and forging a partnership is only the first step to realizing the strategic objectives of a licensing deal. A deal can only be carried out when all parties involved demonstrate their organizational capabilities and effectively allocate resources.

We believe that the management of licensing deals should pivot from "individualism/opportunism" (with reliance on individual professionals) to "collectivism (with reliance on inter-functional collaboration). It should then progress to incorporate "endemic/characteristics" into the management system to serve development needs. Furthermore, considering the licensing deal, other than the licensor and licensee, various third-party service institutions (including those providing pre-clinical research and clinic trials and producing products for trial/commercial uses) should also be incorporated into the entire management process.

Therefore, Chinese pharmaceuticals/medical device companies—either to cope with the domestic operational pressure or to expand overseas markets—should enhance their management of licensing deals to maximize the value of licensed products.

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