环球律师事务所
GLOBAL LAW OFFICE

36th YEARS GLOBAL LAW OFFICE 1984-2020

Foreign Investment in Life Sciences & eHealthcare in China

中国首家律师事务所
The First Chinese Law Firm
www.glo.com.cn

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Partner of Life Sciences Team

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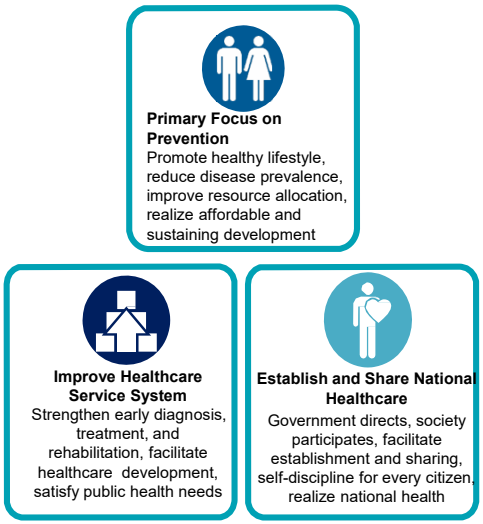
Overview of Legal Framework

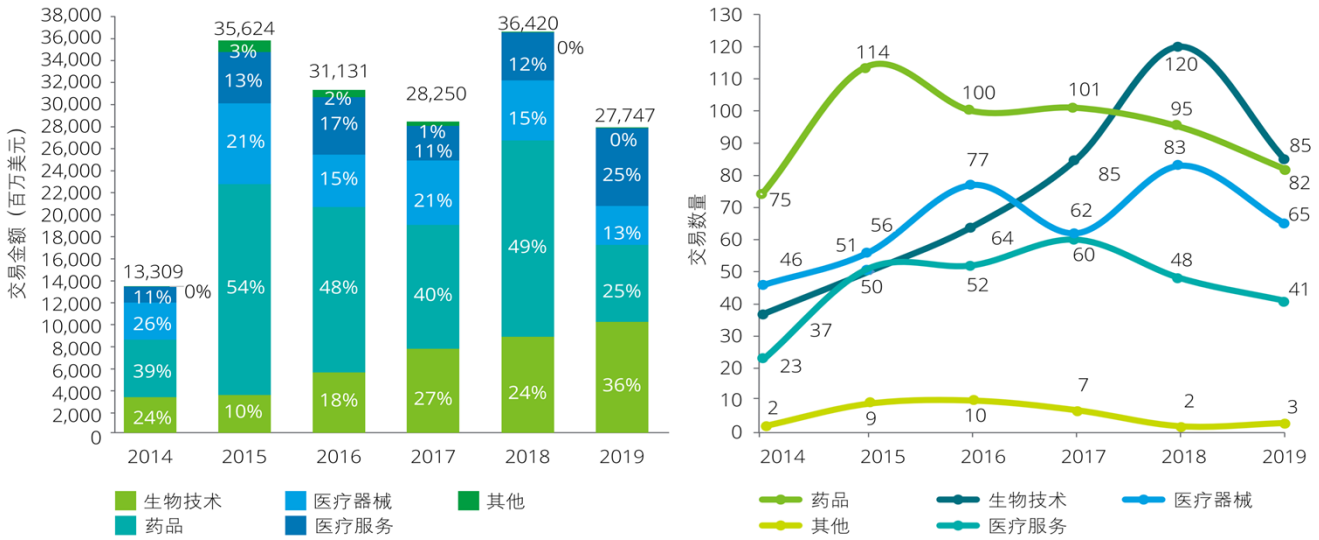
Plan and Outline of "Healthy China 2030" Published

Persist in being goal-oriented and issue-driven, highlight the concept of big health and general wellness, combine long-term development and current foothold, emphasize "basing on general people and entire life cycle", separately deal with the healthcare service issues of being "fairly available" and "systematically continuous" in order to cover the general people and entire life cycle.



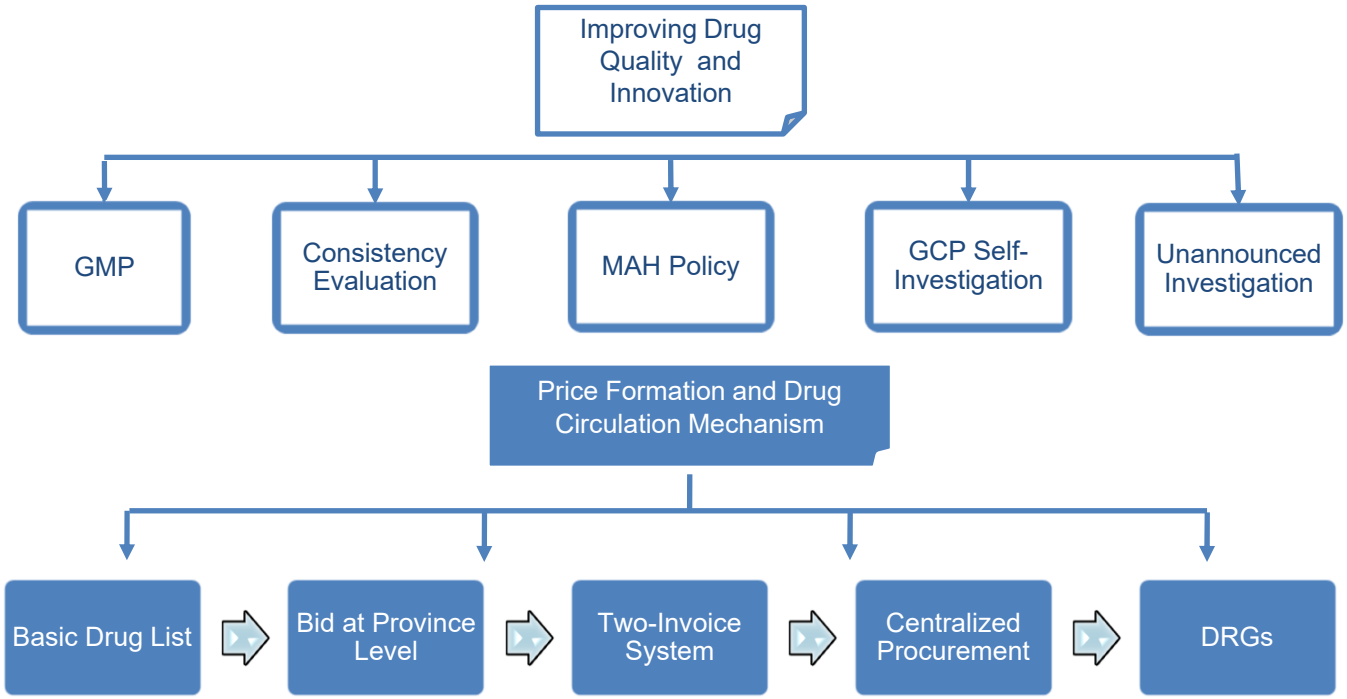
Life science transaction status

图7：生命科学与医疗行业并购交易金额和交易数量，按行业划分（2014年至2019年）

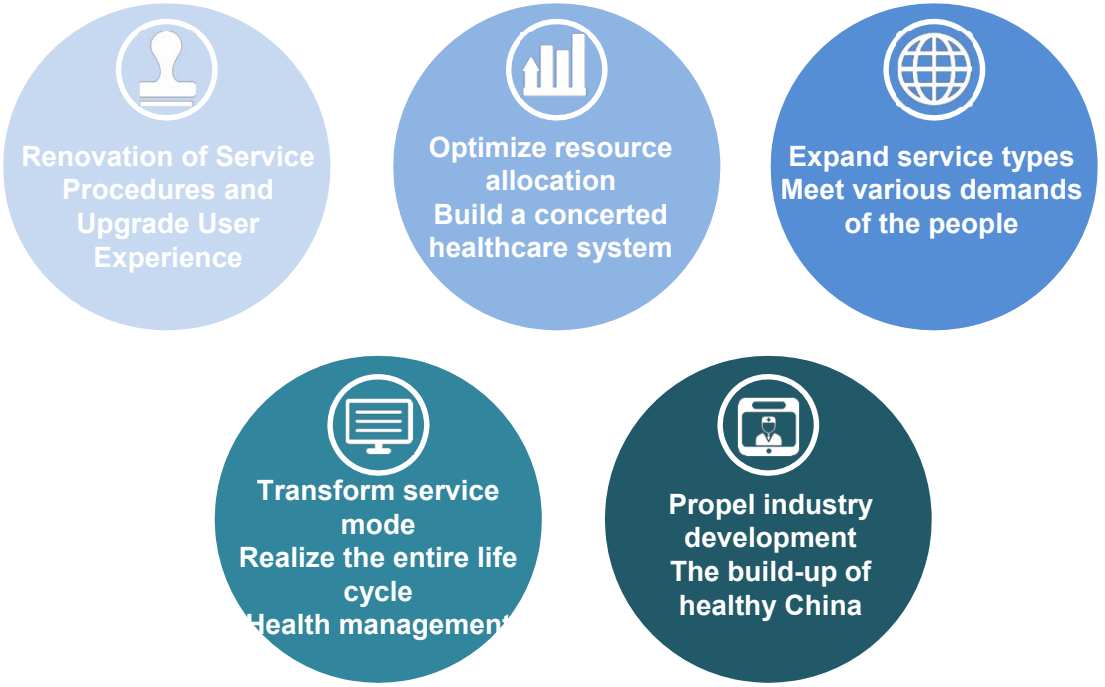


注：为了使交易规模具有可比性，上述交易数量不包括271笔未披露交易金额的交易。
来源：MergerMarket，德勤研究

Authority –Operational Level



E-Healthcare contribute to the build-up of Healthy China



Investment Catalogue

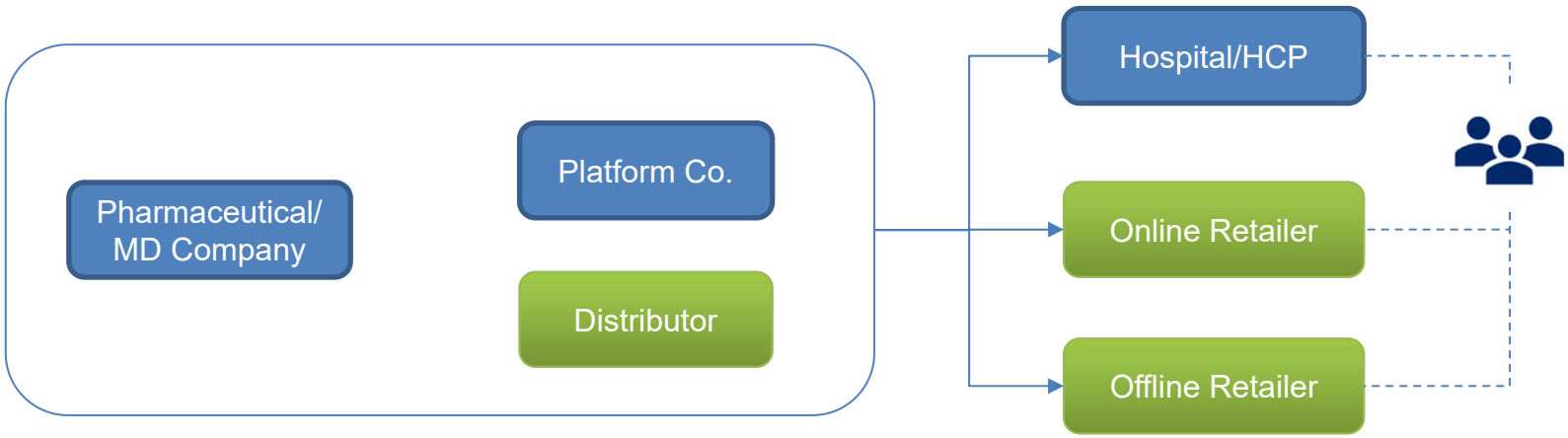
Special Administrative Measures for Foreign Investment Access (Negative List) (July 23th, 2020)

- Prohibited to invest in Chinese herbal medicines and processing technology
- Prohibited to invest in the development and application of human stem cells and gene diagnosis and treatment technologies.
- Medical services is limited to JV, with 70% shareholding cap for foreign investment
- Value-add telecommunications services is limited to JV, with 50% shareholding cap for foreign investment (except for ecommerce, domestic multi-party communications, storage-forwarding and call centres)

Authority – Investment Level

Authority	Responsibility	Permits
NDRC	Investment project	Approval/filing for fixed assets investment (site construction)
SAMR	Company registration	Business license
MOFCOM	Foreign investment supervision	Self-filing in online system
NHC	Medical institution	Practice license for medical institution
NMPA	Drug/medical device	License for drug manufacturing/distribution License/filing for medical device manufacturing/distribution
MIIT	Telecommunication administration	ICP permit/filing (information service via internet) EDI license (data handling platform, E-commerce platform) SP license (mainly SMS services)

Business Model



- Tele-Medicine
- Consulting

- Product retail

- Patient education

- Product/brand promotion

Main Legal Issues for E-health

Qualification	Payment	Promotion	Data
Telemedicine	Anti-bribery	Advertising of MD	Personal information
Healthcare Consulting		Advertising of medical services	Big data
Online sale of Drug/MD			

02

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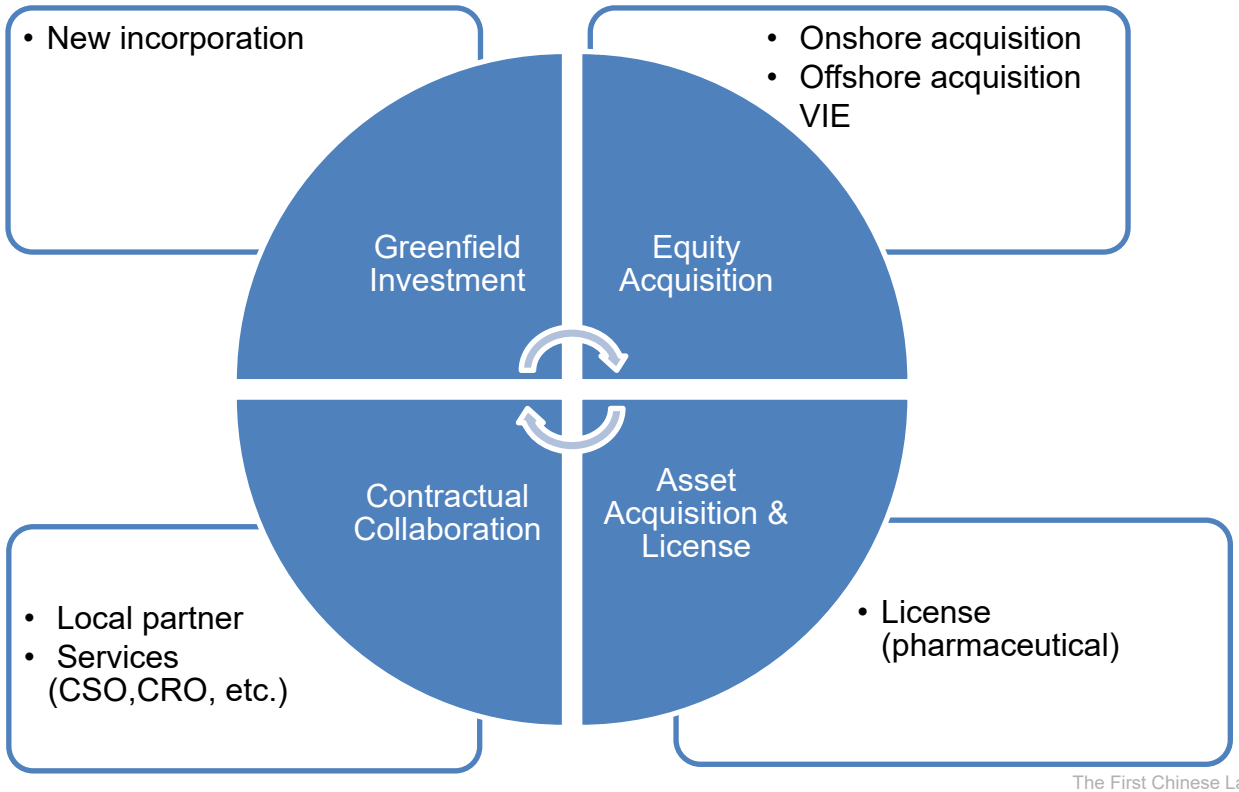
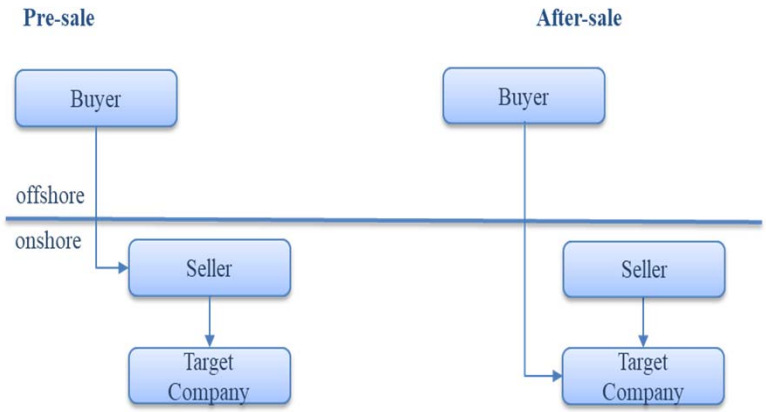
Investment Model

Part II - Investment Model

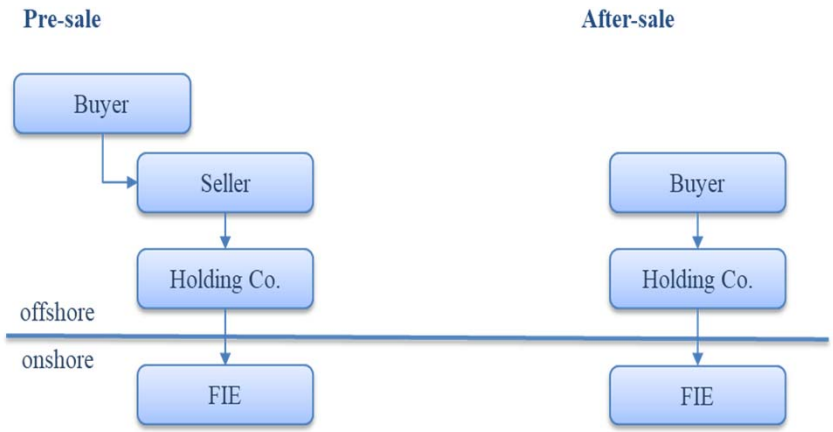


Equity Acquisition

Onshore



Offshore



Equity Acquisition

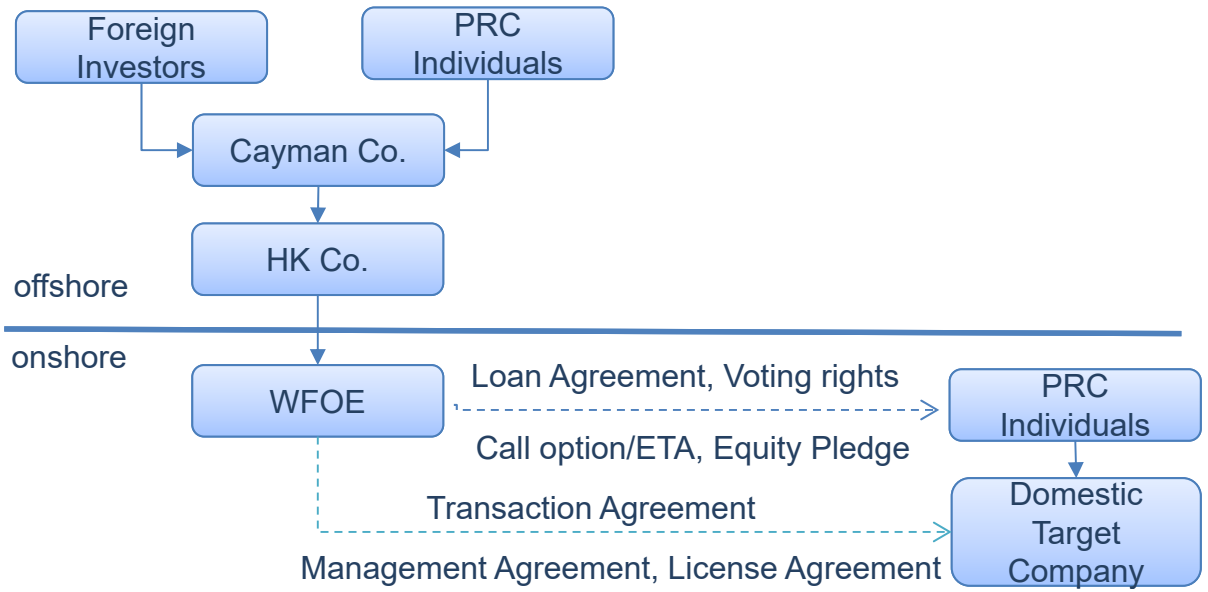
Pros:

- No PRC approval required, other than merger control review (and SAFE registration if the selling shareholder or beneficiary owner is a PRC national)
- Greater flexibility in structuring deal:
  - No statutory appraisal requirements;
  - Preferred shares may be issued;
  - More flexible payment mechanism permitted
- Fewer foreign exchange risks
- Intellectual property remains offshore

Cons:

- Only an option if the Target is an FIE (neatly owned by an offshore holdco)
- May not eliminate the need to restructure underlying PRC subsidiaries
- May not avoid liabilities of or claims against the Target

VIE structure



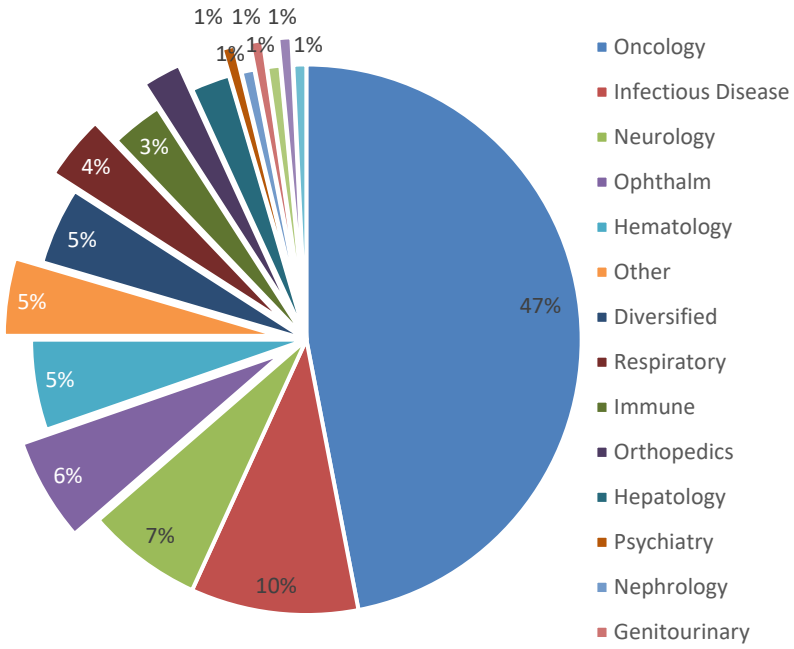
Part II - Investment Model

	WFOE+VIE (split of business)	WFOE+VIE (fully operated by VIE)	WFOE+Uncontrolled Domestic Company ("UDC")	WFOE
Foreign Investment Restrictions	√	√	√	WFOE are prohibited to conduct certain business which shall be outsourced
Human Genetic Resources Application/Filing Requirements	Risk for failure of application/filing by VIE exists	Risk for failure of application/filing by VIE exists	No risk for failure of application/filing by VIE	Subject to application /filing
Narrowly Tailored Requirements of the HKEX for VIE	√	×	N/A	N/A
Consolidation of Financial Statements	√	√	×	N/A
Convenience of Products Registration	× (Additional registration process or documents may be necessary)	√	× (Additional registration process or documents may be necessary)	× (Additional registration process or documents may be necessary)
Ownership of Intellectual Property Rights	√	√	× (IP developed by UDC to be transferred to WFOE)	× (IP developed by third party supplier to be transferred to WFOE)
Source of Funds	Funds contributed to WFOE as capital; loan by WFOE to VIE	Funds contributed to WFOE as capital; loan by WFOE to VIE	Funds contributed to WFOE as capital; service fee by WFOE to UDC**	N/A
Flexibility for Restructure	N/A	High cost for transfer of manufacturing plants and drugs certificates to WFOE	High flexibility to restructure (a VIE Agreement between WFOE and UDC)	N/A

License transaction overview – China market

License-in transactions in China of 2019 – Statistics by treatment area

- Leading number of transactions in Oncology
- Number of transactions in infectious disease and neurology take second place



*Pharnex Datamonitor，截至2019年12月31日

Major features of license transaction

Aim at pharmaceutical products with a certain market potential or having been put into the market → Reduce R&D risk and expand asset portfolio and market coverage	**Market potentiality**
Milestone payment mode - Big pharma: reduce risk and cost of early stage R&D - Start-up company: solve the problem of funding for R&D of new drugs	**Risk sharing**
Create a concentrated R&D advantage for a certain product and a higher market share for the drug market for the treatment of a certain disease	**Ensemble**

Types of license transaction

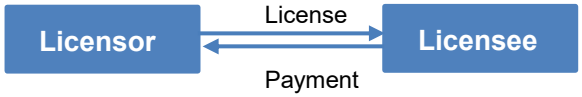
Early stage	R&D and pre-registration stage	Commercialization stage
License of technology/platform • **Common stage:** from drug discovery to drug validation complete • **Licensor:** early stage R&D • **Licensee:** subsequent R&D and clinical trials, and responsible for the manufacture and commercialization of products	**Transfer of results** • **Common stage:** Clinical trials and registrations • **Licensor:** Drug R&D and clinical trials • **Licensee:** registration, manufacture and commercialization of products	**Transfer of commercialization rights** • **Common stage:** After the completion of drug registration • **Licensor:** R&D, registration and manufacture of drugs • **Licensee:** Commercialized operation

From IND to POC to NDA, the main legal risk points, transaction structure design and transaction terms arrangement of new drug R&D project will be different according to the project's clinical risk, investment cost, etc.

Trend of increased compound transactions

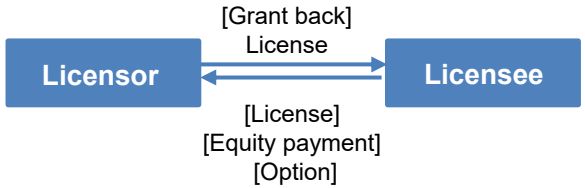
Common license transaction

- First payment
- Progressive/milestone payment
- Sales/license share
- Full Payment in once



Compound transaction with diversified consideration

- Compound transaction
  - Asset swap license
  - Payment of consideration by equity interest/cross shareholding
- Grant back of milestone payment
- Options on geographical/treatment areas



Q&A

Overview

About GLO

The history of Global Law Office dates back to 1984, when it became the first law firm in the People's Republic of China (the "PRC") to take an international perspective on its business, fully embracing the outside world.

In today's global economy, we continue to set the pace as the PRC's most innovative and progressive law firm. In doing so, we build on the energy and creativity of our highly qualified professionals, most of whom have gained qualifications or hands-on experience in law schools and firms throughout Asia, North America, Europe and Australia.

Our clients are the most important part of our business. We have attracted clients from all parts of the world, working in countless industries and market areas.

Our value is delivered to our international and domestic clients through our deep knowledge and experience across the full range of practice areas and industries affected by Chinese law. As one of the country's most well-established and respected firms, we can bring our clients the legal and cultural understanding needed for long-term success in the PRC.

The First Chinese Law Firm
500+ Lawyers

BEIJING SHANGHAI SHENZHEN CHENGDU

Unparalleled Recognition Among Clients

“Client Service Law Firm of the Year – China”

GLO won *Chambers and Partners*’ Client Service Law Firm of the Year – China awards in 2012 and 2018.

CHAMBERS AND PARTNERS

Life-Sciences and Healthcare

Fully dedicate team with" one-stop service"

Global's Life Science & Healthcare (L&H) Practice Group is probably the Only PRC firm with a fully dedicated team to provide "one-stop" legal services for every sector of the L&H industry, including drug R&D, clinical research organizations (CRO), pharmaceuticals, Life Science, biotechnology, medical devices, supply producers and distributors, M&A of privately-owned hospitals, reform and restructuring of public hospitals, securities offering, Greenfield investment and various investment funds in the L&H sector.

Always in the leading position for current development in the industry

Global has worked on reform and restructuring of public hospitals, structuring the relevant deals creatively and innovatively to achieve the clients' commercial objectives in the imprecise and unified L&H regulatory environment. In the past year, Global's L&H group used its perfect combination of international experiences and local knowhow to counsel various clients on the new business trends in China including "portable medical devices", "mobile medical platform", health institute in different form and structures.

Expertise

Close working relationships with Leading pharmaceutical companies, investment funds and healthcare clients

Global routinely advises leading multinational Life Science & Healthcare companies such as Siemens, Abbott, Abbive, Cardinal, Zeiss, MSD, Sanofi, Pfizer, Hospira, Bayer, Novartis, Boehringer Ingelheim, Catalent, Baxalta and Tessenderlo, and local Life Science & Healthcare companies including Shanghai Pharma, China Resources Pharmaceutical, Beijing Pharma, CITIC Medical & Health Group. Global has also advising a number of international and domestic funds in making investments in L&H area, such as Hony Capital, Sequoia Capital, CDH Fund, Legend Capital, Fountain Vest, etc. Global has logged over 40 months of secondment work to these clients with eight associates and counsels other than the responsible partners, essentially running the all legal functions of Boehringer Ingelheim China, Catalent Solution China, Novartis Vaccine and Siemens Healthcare, with minimal support from these companies' in-house teams.

Deep knowledge and expertise in the L&H industry

Global is well positioned to advise clients on most updated challenging L&H legal issues such as compliance and regulatory, structuring industry-specific transactions and contractual arrangements, realization of pipeline and geographic expansions, capital raising and project financing, mergers and acquisitions, reorganizations, IP protection, licensing and distribution arrangements, dispute settlement for adverse effects in clinical trials, medical treatment, etc.

Increasing influence in legislation and the close link to industrial associations

Global also has close links to industrial associations including Association of China Compliance Professionals, China Healthcare Innovation Platform (CHIP), Bio China, RDPAC, CEIBS Healthcare Association, membership in the standing committees of relevant industry code of promotional conduct associations, and has also initiated several research projects with academies, industrial players and governmental bodies on anti-bribery programs and consumer data and privacy protection programs. Global is also the only firm in the legislation program of eHealthcare in China by MOH.

Awards and Rankings in Recent 3 Years

	2020	2019	2018
Chambers and Partners	*Asia and Pacific:* • Band1 Practice Area – Life Sciences & Healthcare • Highly Recommended / Practice Area – Corporate Investigation	*Asia and Pacific:* • Band1 Practice Area – Life Sciences & Healthcare • Highly Recommended / Practice Area – Corporate Investigation	*Asia and Pacific:* • Client Service Law firm of the Year • Band1 practice area – Life Sciences & Healthcare • Highly Recommended / Practice Area – Corporate Investigation
The Legal 500	• Top Tier Practice Area – Life Sciences & Healthcare • Recommended Firm – Compliance	• Top Tier Practice Area – Life Sciences & Healthcare • Recommended Firm – Compliance	• Top Tier Practice Area – Life Sciences & Healthcare • Recommended Firm – Compliance
ASIAN LEGAL BUSINESS 亚洲法律杂志	• Law Firm of the Year – Healthcare, Regulatory Compliance	• Law Firm of the Year – Healthcare, Regulatory Compliance	• Law firm of the Year – Healthcare, Regulatory Compliance
China Business Law Journal		• China Business Law Awards: Healthcare, Pharma & Life Sciences PRC Law Firm of the Year	• China Business Law Awards: Healthcare, Pharma & Life Sciences PRC Law Firm of the Year

Precedents: Life-Science & Healthcare

the largest transaction in Biopharmaceutical Medicine in China

In 2019, we assisted BeiGene to accomplish a strategic transaction globally relative to oncologic sector of Celgene.

the First transaction in biopharmaceutical commercial production under the Market Authorization Holder System of China

we provided legal advices to Boehringer-Ingelheim for its contract manufacturing under the market authorization in biopharmaceutical commercial production and assisted in legal documents drafting.

one of the Largest IPO on the European market in 2018

we participated in the restructuring of healthcare business under the listing project of Siemens medical business sector on Chinese market.

one of the Biggest financing trades in Innovative Medicine in China

we provided legal services for financing Round C of I-MAB that worth $220 million.

one of the Largest M&A in the global pharmaceutical industry

we participated in the global exchange of animal healthcare and non-prescription drugs business between BI and Sanofi.

Alan Zhou | Partner

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Practice

M&A | Compliance

Industry

Life-Sciences & Healthcare

Alan Zhou is the leading partner of Life-sciences and Healthcare Team at Global Law Office, with his strong background in Life-Sciences & Healthcare (L&H) practice. He focuses on M&A, regulatory compliance, and general corporate.

Mr. Zhou has routinely represented multinational corporations, such as Sanofi, Siemens, AstraZeneca, GSK, Abbott, MSD, Boehringer Ingelheim, Novartis, AbbVie, GE, Allergan, Catalent, Hospira, and Terumo, and local Life-Sciences & Healthcare companies including Shanghai Pharma, China Resources Pharmaceutical, Shanghai Industrial Investment, CITIC Medical & Health Group.

As a participant or as an external counsel, Mr. Zhou has been engaged by local authorities and industrial associations for advising on legislation and industrial standard in the L&H industry, topics of which including E-healthcare, medial insurance reform, medical representative administration, and other compliance topics.

Awards

Chambers
Year 2012 – 202p Tier 1 Lawyer in Healthcare (PRC Firms), and a leading lawyer in M&A and Capital Market.

Legal 500
2017-2020 Leading Lawyer in Healthcare and Life-Sciences: PRC Firms.

LEGALBAND
2019-2020 Leading Lawyer in Health care and Life-Sciences.

Asialaw Leading Lawyers
2014 Leading expert in Margin & Acquisition.

Associations and Memberships

CHiPA
Chief Supervisor

CEIBS Healthcare Industry Association
Executive manager

Association of China Compliance Professionals
Council

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Practice

M&A | General corporate | | Cybersecurity & Data Management

Industry

Life-Sciences & Healthcare

Charlene Huang is a partner based in our Shanghai office. She has in-depth experience advising multinational companies in general corporate, cybersecurity, and data management. Most of the clients Charlene represents are in the healthcare industries, including pharmaceutical companies, medical device companies, and private medical institutions.

Charlene Huang frequently provides risk-based advices for multinational companies with respective to product distribution, marketing, and promotion, and she provides overall risk-assessment or health check on specific BU. For cybersecurity and data protection areas, Ms. Huang has advised multinational medical device and pharmaceutical companies (Align Tech, BI, Abbott, Shire, Ferring, etc.) in various projects involving health data utilization, including inter-company system review, digital marketing, innovative E-health projects, and PPP projects.

Latest publications & events

Chambers Global Practice Guide – Pharmaceutical Advertising: China Law & Practice (2020)

GLO Law & Policy Newsletter in Life Science and Healthcare

A Series of Interpretation on the Basic Medical Health and Health Promotion Law -- what course to follow for public hospitals to establish for-profit medical institutions

A Series of Interpretation on the Basic Medical Health and Health Promotion Law -- analysis of policies on establishment of medical institutions with social capital

Education

East China University of Politics and Law	LL.M.
Cardiff University	LL.M.
East China University of Politics and Law	LL.B.

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THANK YOU!
谢谢观看