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TABLE OF CONTENTS / 本期内容

CAPITAL MARKET / 资本市场

Provisions Governing Material Asset Restructuring on STAR Board Released / 科创板上市公司重大资产重组制度出台 2

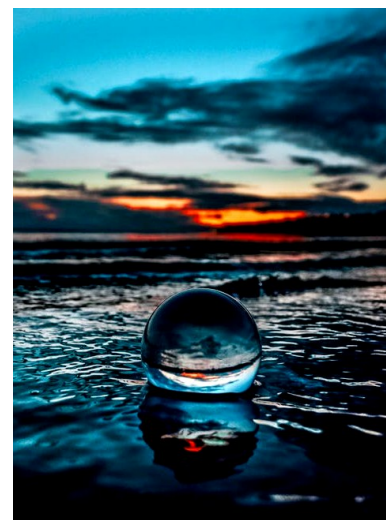
CSRC Released Pilot Scheme for A-Share Listing of Subsidiaries of Listed Companies for Public Comments / 证监会就上市公司子公司境内上市试点征求公众意见 2

HEALTHCARE / 医疗健康

Revisions to Drug Administration Law Issued to Implement Drug MAH Mechanism on a Nation-Wide Basis / 新版《药品管理法》出台，全面实施药品上市许可持有人制度 3

REAL PROPERTY / 不动产

Amendments to Land Administration Law Adopted, Conditionally Allowing Marketization of Collectively-Owned Land Use Rights / 《土地管理法》修订通过，允许集体经营性建设用地有条件流转 4



CAPITAL MARKET / 资本市场

Provisions Governing Material Asset Restructuring on STAR Board Released 科创板上市公司重大资产重组制度出台

2019年8月23日，证监会发布《科创板上市公司重大资产重组特别规定》，明确科创板上市公司（“科创公司”）的并购重组审核也将施行注册制。同日，上海证券交易所（“上交所”）发布《上海证券交易所科创板上市公司重大资产重组审核规则（征求意见稿）》并向社会公开征求意见，进一步细化相关的审核标准、程序和信息披露等要求。

根据上述规定，科创公司重大资产重组的标的应当符合科创板定位，与科创公司处于同行业或者上下游，并与科创公司主营业务具有协同效应。此外，考虑到科创公司的特点，与现行的《上市公司重大资产重组管理办法》（“《重组办法》”）相比，上述规定主要在以下方面进行了调整：(i)延续注册制改革：科创公司重大资产重组涉及发行股份的，由上交所审核，报证监会履行注册程序；不涉及发行股份的，由上交所审核后作出决定；(ii)调整重大资产重组认定标准：科创公司重大资产重组的认定标准除保留《重组办法》中的有关总资产、净资产和营业收入指标要求外，还根据科创公司的营收特点就营业收入的标准，增加了需超过人民币5000万元的财务指标；(iii)放宽发行价格：科创公司发行股份的价格不低于市场参考价的80%，低于《重组办法》规定的发行价格不得低于市场参考价90%的要求。此外，上述规定还明确了科创板可以进行重组上市（即“借壳”），但重组上市门槛较高，除需符合科创板首发上市的相关规定之外，还应符合额外的财务指标要求。

On August 23, 2019, the China Securities Regulatory Commission (the “CSRC”) issued the Special Provisions for Material Asset Restructuring of STAR Board Listed Companies claiming the adoption of a registration-based regulatory system for material mergers and acquisitions of companies listed on the STAR board (the “STAR Companies”). On the same day, the Shanghai Stock Exchange (“SSE”) also released a draft of the Rules Governing Review of Material Asset Restructuring of STAR Board Listed Companies for public comments, further standardizing the detailed requirements for procedures, disclosure obligations and other key aspects.

Pursuant to the above-mentioned rules, the target assets for a proposed material restructuring of a STAR Company shall fall into the business category encouraged by the STAR board, be within the same, the upstream or downstream industries of the STAR Company and have synergistic effects with the core business of the STAR Company. Compared to the Measures for the Administration of the Material Asset Restructuring of Listed Companies (the “Restructuring Measures”), the existing rules governing material asset restructurings of all listed companies, the above-mentioned rules have mainly made the following revisions that are specifically applicable to the STAR Companies: (i) adoption of registration-based regulatory system. For material asset restructurings of STAR Companies involving issuance of new shares, the restructuring shall be verified by the SSE and subject to the registration procedures with CSRC. All the other material assets restructurings will only be subject to the SSE’s review and decision; (ii) adjustment of criteria for qualified material asset restructurings. In addition to the existing three criteria for the assets qualified for the material assets restructurings provided under the Restructuring Measures (i.e., requirements for total assets, net assets and operating income of the target assets), the operating income generated from the target assets in the past fiscal year shall also exceed RMB50 million; and (iii) expansion of the range of issue price. The permitted lowest issue price of the new shares issued for purpose of material asset restructurings of a STAR Company is lowered from 90% of the reference market price as provided under the Restructuring Measures to 80%. In addition, the above-mentioned rules also specified requirements for qualified back-door listings on the STAR board. The target companies intending to go with back-door listings shall not only meet the requirements applicable to initial public offerings (IPO) on the STAR board, but also reach additional financial indicators.

CSRC Released Pilot Scheme for A-Share Listing of Subsidiaries of Listed Companies for Public Comments 证监会就上市公司子公司境内上市试点征求公众意见

2019年8月23日，证监会发布《上市公司分拆所屬子公司境内上市试点若干规定》并向社会公开征求意见（“《试点规定》（征求意见稿）”），首次明确了上市公司可将部分业务或资产，以其直接或间接控制的子公司的形式，在境内证券市场（包括科创板）首次公开发行股票上市或重组上市，并对上市公司境内分拆的实质性条件、程序要求等进行了规定。需注意的是，上市公司不得分拆主要从事金融业务的子公司上市。

On August 23, 2019, the CSRC released a new draft of the *Several Provisions on the Pilot Scheme of Domestic Listing of Subsidiaries of Listed Companies through Corporate Spin-Off* (the “Draft Provisions”) for public comments, which for the first time permitted a listed company to split off part of its business or assets to one of the subsidiaries directly or indirectly controlled by it and then to apply for independent IPO or back-door listing of such subsidiary on China’s A-share market (including the STAR board), and set forth specific requirements and procedures for the qualified corporate/assets spin-off of the listed companies. Note that, however, according to the Draft Provisions, if a subsidiary of a listed company is mainly engaged in financial business, it may not apply for an independent A-share listing through a corporate or asset spin-off.

HEALTHCARE / 医疗健康

Revisions to Drug Administration Law Issued to Implement Drug MAH Mechanism on a Nation-Wide Basis 新版《药品管理法》出台，全面实施药品上市许可持有人制度

2019年8月26日，第十三届全国人大常委会第十二次会议表决通过了新修订的《药品管理法》（“2019年《药品管理法》”），将于2019年12月1日起施行。2019年《药品管理法》吸收了近年来药品管理改革的试点成果，并通过立法正式确立了相关制度，主要修订内容包括：

1. **全面实施药品上市许可持有人制度：**按照此前的药品管理法规，我国药品监管采用上市许可与生产许可捆绑的模式，即药品上市许可（药品批准文号）只颁发给具有药品生产资质的生产企业，且药品上市许可无法转让。自2015年11月起，部分省市开展了药品上市许可持有人（MAH）制度试点，允许拥有药品技术的研发机构申请成为药品上市许可持有人，在取得药品注册证书及药品上市许可后，以自己的名义将产品投向市场并对药品全生命周期承担责任。2019年《药品管理法》确立了MAH制度的全面推行，并进一步明确：**(i)**药品上市许可持有人可以依法自行生产、销售药品（如取得药品生产及经营资质）或委托药品生产企业生产药品、委托药品经营企业销售药品；以及**(ii)**药品上市许可可以依法转让。
2. **取消GMP/GSP认证：**2019年《药品管理法》删除了药品生产质量管理规范（GMP）认证、以及药品经营质量管理规范（GSP）认证，并将有关要求分别纳入药品生产许可和药品经营许可条件。
3. **调整临床试验审批机制：**国家药品监督管理局此前曾发布相关公告及政策意见，将药物临床试验的审批制度调整为默示许可制（即申请受理之日起六十个工作日内未收到主管部门通知的，申请人可自行开展临床试验）、临床试验机构的认证管理调整为备案管理。2019年《药品管理法》进一步落实了上述制度改革，以提高临床试验管理效率、鼓励新药研发。

除了以上内容，2019年《药品管理法》还对网络销售药品、药品质量追溯制度、假药劣药认定、药品违法行为处罚等规则进行了修订与完善。我们理解，2019年《药品管理法》颁布后，相关配套规定也将陆续修订并发布，我们将对此保持持续关注。

On August 26, 2019, China released the revisions to the *Drug Administration Law* (the “2019 Revisions”) which will take into effect on December 1, 2019. The 2019 Revisions have incorporated several reforms of drug administration previously implemented in some pilot areas and set forth below are some noteworthy highlights in the 2019 Revisions:

1. **Nation-wide Implementation of Drug MAH Mechanism.** Marketing authorizations (i.e., *drug approval number*) for a drug used to be tied to the drug production license (i.e., *only a qualified pharmaceutical manufacturing company can apply for and obtain drug approval number for a drug and get the drug commercialized*) and the drug approval number of the drug was not allowed to be transferred. Since November 2015, the drug marketing authorization holder (the “MAH”) mechanism has been piloted in several provinces, which allowed a qualified drug R&D entity to be recognized as a MAH and issued drug approval number of a drug. Under the drug MAH mechanism, while the R&D entity who is a MAH remains responsibilities for the full “life cycle” of the concerned drug (including, among others, clinical trials, manufacturing, selling, and the analysis of and response to adverse reactions), it could contract out the production and/or sales of the drug to other qualified pharmaceutical companies. According to the 2019 Revisions, the drug MAH mechanism will soon be implemented on a nation-wide basis with the following fundamental principles that: (i) subject to applicable requirements, qualifications and certain exceptions, a MAH can either produce or commercialize the concerned drugs on its own, or contract out production or sales of the drugs to qualified third-parties; and (ii) the marketing authorizations obtained by a MAH with respect to a drug can be transferred upon approval.
2. **Cancellation of GMP and GSP Certifications.** The 2019 Revisions cancelled the Certifications for Good Manufacturing Practice (GMP) and Good Supply Practice (GSP), and consolidated relevant requirements into the qualifications of applicants for Drug Production Licenses and Drug Trading Licenses.
3. **Adjustment of Administration for Clinical Trials.** To enhance the efficiency of administrations on clinical trials and spur drug innovation, the 2019 Revisions confirmed and will further implement the implied permission system for clinical trials (i.e., *an applicant is allowed to start clinical trials for the relevant drugs if no notice is received from competent authorities within 60 working days since its application*) and the filing-based administration system for certification of clinical trial institutions established through policies issued by the National Medical Products Administration.

In addition to the above, the 2019 Revisions also amended and refined regulations governing such key areas as online drug sales, traceability mechanism on drug quality, scope of fake drugs and inferior drugs and punishments for illegal acts. To further implement the 2019 Revisions, revisions to existing rules which are inconsistent with the 2019 Revisions and some detailed implementing rules are expected to be further promulgated and released. We will continue to monitor and timely update interested investors of major developments in this connection.

REAL PROPERTY / 不动产

Amendments to Land Administration Law Adopted, Conditionally Allowing Marketization of Collectively-Owned Land Use Rights 《土地管理法》修订通过，允许集体经营性建设用地有条件流转

2019年8月26日，第十三届全国人大常委会第十二次会议表决通过了经修订的《土地管理法》（“2019年《土地管理法》”），将于2020年1月1日起施行。允许集体经营性建设用地入市是此次《土地管理法》修改的最大亮点。

根据现行的《土地管理法》及其他相关规定，集体经营性建设用地和宅基地不得出让、转让或者出租给农村集体经济组织以外的单位或个人，必须通过征收转为国有土地后才能进行流转。为有效利用土地资源，结合近年来农村土地制度改革的试点经验，2019年《土地管理法》删除了相关的禁止性规定，并进一步明确：**(i)**农村集体经营性建设用地在符合规划、依法登记，并经三分之二以上集体经济组织成员同意的情况下，可以通过出让、出租等方式交由农村集体经济组织以外的单位或个人直接使用，**(ii)**使用者在取得农村集体经营性建设用地之后还可以依法通过转让、出资、抵押等方式进行再次转让。对于宅基地流转问题，《土地管理法》（2019年修订版）虽未作明确，但删除了相关的禁止性规定，有利于各地按照中央政策要求开展宅基地“三权分置”（即所有权、使用权及资格权）改革，为盘活利用闲置宅基地和闲置住宅留下了空间。

我们理解，随着2019年《土地管理法》的出台，国务院及各地主管部门将会陆续出台具体的实施办法或细则，对于实践中已经存在的农村集体经营性建设用地和宅基地流转应该也会逐步规范、整改，我们将对此保持持续关注。

On August 26, 2019, the *Amendments to Land Administration Law* (the “2019 Amendments”) were formally adopted, which will take into effect on January 1, 2020.

The brightest spot of the 2019 Amendments is to conditionally allow the marketization of land use rights of qualified rural collectively owned profit-oriented construction land. Pursuant to the existing Land Administration Law and other applicable regulations, generally speaking, the right to use rural collectively-owned construction land (including profit-oriented construction land and the rural residential construction land) is not allowed to be sold, transferred, leased or otherwise circulated (collectively, “Circulate” or “Circulation”) to any person or entity who is not a member of the rural collective economic organization owning such land (the “Land Owner”) unless the land concerned is expropriated and converted into state-owned land. To optimize effective use of land resources and based on previous pilot reforms, the 2019 Amendments lifted the relevant restrictions and explicitly allowed that: **(i)** the use right of a piece of rural collectively-owned profit-oriented construction land could be Circulated to a person who is not a member of the Land Owner (the “Qualified User”) provided that such Circulation conforms to the land planning and registration requirements, and has been approved by over two-thirds of the members of the Land Owner; and **(ii)** the Qualified User may further Circulate the relevant land use right by means of transfer, capital contribution or pledge subject to implementing rules to be released by the State Council. It is also noteworthy that, though the 2019 Amendments keep silent on the Circulation of the use right to the rural residential construction land, the amendments have deleted relevant prohibitive provisions, which is deemed as an effort to leave space for local reforms with respect to separation of the ownership, use right and qualification right of the rural residential land for better and efficient use of idle rural residential land and houses.

With the adoption of the 2019 Amendments, we believe relevant implementing rules will be issued by the State Council and local land bureaus, meanwhile in practice, the existing local rules, policies and practice with respect to Circulating use right to rural collectively-owned construction land are likely to be gradually adjusted to conform to the 2019 Amendments. We will continue to monitor and timely update interested investors of major developments in this connection.

These updates are intended for information purpose only and are not a legal advice or a substitute for legal consultation for any particular case or circumstance. © Han Yi Law Offices All Rights Reserved.

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