CHINA
REGULATORY UPDATES

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CAPITAL MARKET / 资本市场

New Regulations on Issuance of Overseas GDRs Landed 境外发行GDR新规落地

继2023年2月17日发布《境内企业境外发行证券和上市管理试行办法》（“试行办法”）及其5项配套监管规则（*具体分析请见我所《每月立法动态》2023年2-4月刊*）后，中国证券监督管理委员会（“证监会”）于2023年5月16日发布了《监管规则适用指引——境外发行上市类第6号：境内上市公司境外发行全球存托凭证指引》（“6号指引”），对境内上市公司境外发行可转换为境内基础股份的存托凭证（即全球存托凭证或GDR）的定位、申请程序、规则适用、材料要求和实施安排等方面进行了具体规定，以进一步完善境外上市备案管理制度规则。上海证券交易所和深圳证券交易所随后也就修订后的互联互通存托凭证上市交易暂行办法向社会公开征求意见（“征求意见稿”），细化了交易所上市公司境外发行GDR的发行条件、审核安排和信息披露要求。

6号指引及征求意见稿基于《存托凭证发行与交易管理办法（试行）》《境内外证券交易所互联互通存托凭证业务监管规定》等现有规定，优化完善了境内上市公司境外发行GDR的规则，并落实了全面实施股票发行注册制和境外上市备案管理制的精神，预计将会对GDR发行产生以下重要影响：

1. 明确了申请流程和适用规则。在试行办法及6号指引发布之前，境内上市公司可以直接向证监会提交发行GDR申请，证监会在核准发行GDR的批复中同时明确其境内新增基础股票发行事宜，不需要经境内证券交易所审核。而6号指引明确将GDR境内新增基础股票的发行纳入注册管理，由境内证券交易所参照上市公司向特定对象发行股票的程序进行审核、报证监会注册，而GDR的发行及上市则需向证监会备案（证监会也可以将增发股份的注册与GDR备案合并办理）。这意味着GDR发行将会涉及到证券交易所、证监会发行部与国际部等多个部门的协调监管，合规要求也进一步提高。

2. 加强对发行门槛及募集资金用途的监管。在6号指引发布之前，监管规定对于境内上市公司境外发行GDR的市值、募集资金的用途等方面并未明确限制，主要取决于境外证券交易所的要求。6号指引则明确指出，发行GDR的境内上市公司应为“具有一定市值规模、规范运作水平较高”的公司，征求意见稿则进一步明确了以境内新增股票为基础证券发行GDR的公司，应当已在上海或深圳证券交易所上市满1年，且发行申请日前120个交易日的平均市值不低于人民币200亿元。此外，6号指引规定GDR募集的资金应当用以“投向符合国家产业政策的主业领域”，并按照《上市公司监管指引第2号——上市公司募集资金管理和使用的监管要求》规范使用募集资金。发行人在提交证监会及证券交易所的注册申

Following the announcement of the *Trial Administrative Measures for the Issuance and Listing of Overseas Securities by Domestic Companies* (the “Trial Measures”) and its five supporting guidelines on Feb 17, 2023 (*please refer to our Feb-April 2022 issue of China Regulatory Updates*), the China Securities Regulatory Commission (the “CSRC”) issued the *Guidelines on Application of Regulatory Rules —Overseas Issuance and Listing No. 6: Guidelines on Overseas Issuance and Listing of Global Depository Receipts by Domestically Listed Companies* (the “No. 6 Guideline”) on May 16, 2023. The No. 6 Guideline provides specific provisions on the positioning, application processes, rules application, document requirements, and implementation arrangements for the issuance of depositary receipts convertible into underlying domestic shares (i.e., Global Depositary Receipts or GDRs) by domestic listed companies. This aims to further improve the rules and regulations for overseas listing filings management. The Shanghai and Shenzhen Stock Exchanges subsequently solicited public comments on the amended *Draft Interim Measures for the Listing and Trading of Depositary Receipts under the Stock Connect Scheme* (the “Draft Interim Measures”), which further refined the issuance conditions, review arrangements, and information disclosure requirements for the overseas issuance of GDRs by domestic listed companies.

The No. 6 Guideline and the Draft Interim Measures are built on existing regulations such as the *Administrative Measures for the Issuance and Trading of Depositary Receipts (for Trial Implementation)* and the *Regulatory Provisions on Depository Receipts under the Connect Scheme between Domestic and Overseas Stock Exchanges*. They optimize and improve the rules for the issuance of GDRs, and implement the registration-based IPO system and the overseas listing filings system on a full scale. The No. 6 Guideline is expected to have the following significant effects on the issuance of GDRs:

1. Clarified the application process and applicable rules. Prior to the release of the Trial Measures and No. 6 Guideline, domestic listed companies could directly submit GDR issuance application to the CSRC. CSRC will simultaneously specify the issuance of new domestic underlying shares in the approval of GDR issuance, without the need for review by the stock exchanges. However, the No. 6 Guideline explicitly requires registration for the issuance of new domestic underlying shares for GDRs, and the stock exchange will review and report to CSRC for registration in accordance with the procedures applicable to private placements by listed companies. Meanwhile, the issuance and listing of GDRs require filing with the CSRC (CSRC may also combine the registration of additional share issuance with GDR filing). This means that the issuance of GDRs will involve coordination and supervision by multiple departments, such as the securities exchange, the CSRC issuance department and the international department, and the compliance requirements will be further enhanced.

2. Strengthened supervision of issuance criteria and use of funds. Prior to the release of the No. 6 Guideline, the regulatory requirements for the market value of the GDR issuers and the use of raised funds were limited and mainly subject to the requirements of overseas securities exchanges. The No. 6 Guideline specifies that domestic listed companies issuing GDRs should be companies with “a certain market value scale and a higher level of standardized operations”. The Draft Interim Measures further specify that GDRs issuers with domestic shares as

请或备案材料中，也需就其是否符合上述监管要求进行说明。

3. 对发行间隔提出要求。根据6号指引的规定，GDR的发行间隔应参照境内上市公司增发、配股等再融资的发行间隔规定（即本次发行董事会决议日距离前次募集资金到位日原则上不得少于十八个月，前次募集资金基本使用完毕或者募集资金投向未发生变更且按计划投入的，相应间隔原则上不得少于六个月）。此前，监管规定并未明确GDR适用的发行间隔，实践中也存在GDR突破再融资发行间隔的案例，这也被视为GDR作为融资工具的优势之一。随着6号指引的实施，市场普遍认为GDR的发行间隔优势将不复存在，有利于引导上市公司理性融资。

4. 明确过渡期安排。根据6号指引的规定，2023年3月31日前，已在境外提交GDR的发行申请，但未获证监会核准的，应当履行基础股份发行注册及境外发行上市备案程序；已经股东大会审议通过的，无需重新提交股东大会审议。

underlying securities should have been listed on the Shanghai or Shenzhen Stock Exchanges for at least one year. Also, the average market value of the consecutive 120 trading days prior to the application date should not be less than RMB 20 billion. In addition, the No. 6 Guideline stipulates that the raised funds should be "invested in their principal business areas which comply with national industrial policies" and should be used in accordance with the *Regulatory Guidelines for Listed Companies No.2 — Regulatory Requirements for the Management and Use of Funds Raised by Listed Companies*. Issuers are also required to demonstrate their compliance with the above requirements in their registration applications or filing materials submitted to the CSRC and the applicable stock exchange.

3. Requirements for issuance intervals. According to the No. 6 Guideline, the issuance interval for GDRs should be consistent with the intervals for new shares issuance, share allotments, and other refinancing instruments by domestic listed companies (i.e., the interval from the date of the board resolution of the current issuance to the date when the previously raised funds are in place should generally not be less than eighteen months. If the previously raised funds have been almost used up or invested as planned without change, the corresponding interval should generally not be less than six months). Previously, there were no clear requirements regarding the issuance intervals for GDRs. In fact, there were cases where such issuance interval was shorter than that for other refinancing methods, which was seen as one of the advantages of GDRs. With the implementation of Guideline No. 6, the market generally believes that the advantage of shorter issuance intervals for GDRs will no longer exist. This change is expected to encourage listed companies to pursue rational financings.

4. Transitional arrangements. According to the No. 6 Guideline, those who have submitted an application for GDR issuance overseas before March 31, 2023 but have not been approved by the CSRC should register the issuance of underlying shares and file for overseas listing. Those that have been approved by the shareholders' meeting do not need to resubmit them for approval by the shareholders' meeting.

LIFE SCIENCE / 生命科学

The Implementing Rules for the Administration of Human Genetic Resources Released 《人类遗传资源管理条例实施细则》正式稿发布

2023年6月1日，中国科学技术部（"科技部"）正式发布了《人类遗传资源管理条例实施细则》（"实施细则"），自2023年7月1日起正式实施。实施细则基于《中华人民共和国生物安全法》及《中华人民共和国人类遗传资源管理条例》（"管理条例"）等现有法律法规、科技部的相关官方问答以及监管实践，针对我国人类遗传资源的采集、保藏、利用以及对外提供等相关行政程序进行了细化规定，为开展人类遗传资源相关活动提供了更明确的合规指引。此外，相比于此前科技部发布的《人类遗传资源管理条例实施细则（征求意见稿）》（"征求意见稿"）（*具体分析请见我所《每月立法动态》2022年2月刊*），实施细则进行了一定的优化和精简，主要包括以下方面：

1. 细化"外方单位"的认定标准。根据管理条例，外方单位（即外国组织及外国组织、个人设立或者实际控制的机构）不得在我国境内采集、保藏

On June 1, 2023, the Ministry of Science and Technology of China ("MOST") officially released the *Implementing Rules for the Administrative Regulation on Human Genetic Resources* (the "Implementing Rules"), which has come into effect on July 1, 2023. The Implementing Rules, based on existing legislations such as the *Biosecurity Law of the People's Republic of China* and the *Administrative Regulations on Human Genetic Resources* (the "HGR Regulation"), MOST's Q&As, and regulatory practices, provide detailed provisions on the administrative procedures for the collection, preservation, utilization, and external provision of human genetic resources in China. Compared to *the Draft Implementation Measures of the Administrative Regulations on Human Genetic Resources* (the "Draft Measures"), the Implementing Rules have been further optimized and streamlined, primarily in the following aspects:

1. Refinement of criteria for what will consitutute "foreign entities". According to the HGR Regulation, foreign entities (i.e., foreign organizations and individuals and the institutions formed or actually controlled by them) are not allowed to collect, preserve human genetic resources in China or provide Chinese human genetic resources to

我国人类遗传资源，不得向境外提供我国人类遗传资源，相关办事指南同时规定了港澳台组织及港澳台组织、个人设立或者实际控制的机构参照外方单位管理。由于管理条例及相关办事指南并未对“设立”、“实际控制”等界定外方单位的具体标准进行说明，导致实践中对于含有少量外资成分的机构是否属于外方单位存在争议。征求意见稿对于“实际控制”的情形进行了细化规定（包括通过股权控制、表决权控制、协议安排/VIE控制以及作为兜底的其他法定情形），而实施细则进一步明确无论是境外主体“设立”还是“实际控制”的机构，均需要从境外主体是否构成对该机构“实际控制”的角度界定是否属于外方单位，并且新增规定了“设在港澳的内资实控机构视为中方单位”。目前“内资实控”的含义并不明确，如参照判断境外主体“实际控制”的情形，境内创始人控制的红筹架构企业是否可被视为中方单位，有待监管机构的进一步澄清。

2. 限缩“人类遗传资源信息”的范围。根据管理条例，所有利用人类遗传资源材料（即含有人体基因组、基因等遗传物质的器官、组织、细胞等遗传材料）产生的数据等信息资料均属于“人类遗传资源信息”，该范围较为宽泛，实践中对于企业和机构从事相关的数据活动增加了不必要的行政程序和沟通成本。征求意见稿将“人类遗传资源信息”限缩为利用人类遗传资源材料产生的“人类基因、基因组数据”等信息资料，实施细则在此基础上进一步将“临床数据、影像数据、蛋白质数据和代谢数据” 等四种数据类型明确排除在人类遗传资源信息范畴外，因此利用该等数据类型无须履行人类遗传资源相关许可、备案或报告等程序，有利于减轻企业和机构的行政负担，但应注意还需符合个人信息保护和数据出境的相关规定。

3. 完善伦理审查的要求及依据。征求意见稿规定，外方单位在满足特定条件下可申请豁免外方伦理审查。实施细则取消了该条款，转而规定若外方单位确实无法提供所在国（地区）伦理审查证明，则允许其提交外方单位认可中方单位的伦理审查意见的证明材料，这一修改在鼓励跨境合作的同时，确保了人类遗传资源相关活动应经过伦理审查的原则。此外，对比征求意见稿，实施细则规定了开展伦理审查应当遵守法律、行政法规和国家有关规定，而非仅参照国家卫生健康行政部门的特定规定。这一修改增加了伦理审查依据的灵活性，并为考虑其他相关规定（如科技部已发布的《科技伦理审查办法（试行）（征求意见稿）》）提供了适用空间，有助于适应未来科技伦理领域的发展和变化。

overseas entities. In addition, the relevant guidelines provide that entities of Hong Kong, Macau and Taiwan, as well as those established or effectively controlled by individuals from Hong Kong, Macau, and Taiwan, are generally managed in the same way as foreign entities. However, as the HGR Regulation and the relevant guide do not explain the terms of “established” or “actually controlled”, there have been controversies in practice about whether entities with a small amount of foreign capital should be treated as foreign entities. The Draft Measures elaborated on “actual control” (including control through equity, voting rights, contractual arrangements/VIEs, and other situations), while the Implementing Rules further specify that whether an institution is considered a foreign entity should be determined from the perspective of whether the overseas entity has “actual control” over that institution, regardless of whether the institution is “established” or “actually controlled” by a foreign entity. The Implementing Rules additionally state that “domestically controlled organizations established in Hong Kong/Macao shall be deemed as Chinese entities”. The meaning of “domestically controlled” is not clear, and further clarification is needed from regulatory authorities to determine whether red-chip structured companies controlled by domestic founders can be considered Chinese entities.

2. Restriction on the scope of “information on human genetic resources”. According to the HGR Regulation, all information materials such as data generated from the utilization of materials of human genetic resources (i.e., organs, tissues and cells which contain human genomes, genes and other genetic substances) are considered “information on human genetic resources”. This scope is relatively broad, which has added unnecessary administrative procedures and communication costs for enterprises and institutions engaged in related data activities. The Draft Measures narrowed down the scope to “information materials such as human genes and genome data generated by using human genetic resources materials”, and the Implementing Rules specifically exclude four types of data—“clinical data, image data, protein data and metabolic data”—from the scope. The utilization of these four types of data thus no longer requires compliance with the license, filing, or reporting procedures related to human genetic resources, reducing the compliance cost for enterprises and institutions. However, it should be noted that compliance with relevant regulations on personal information protection and cross-border data transfer is still required.

3. Improvement of the requirements and legal basis for ethical review. The Draft Measures provided that foreign entities, under specific conditions, could apply for an exemption from ethical review. The Implementing Rules remove such clause and further specify that if a foreign entity is indeed unable to provide proof of ethical review from the country (region) where it is located, it may submit proof of ethical review from a Chinese entity recognized by the foreign entity. This amendment encourages cross-border cooperation while ensuring that human genetic resources-related activities should always undergo ethical review. Further, compared to the Draft Measures, the Implementing Rules provide that ethical reviews should comply with laws, administrative regulations, and relevant national regulations, rather than merely referring to specific regulations from the National Health Administration department. This amendment increases the flexibility of the basis for ethical reviews and provides room for consideration of other relevant regulations (such as the *Draft Method for Scientific Ethical Review (Trial)* issued by the Ministry of Science and Technology), which is conducive to adapting to the future development and changes of scientific ethics.

DATA SECURITY / 数据安全

The Cyberspace Administration of China Issued *Guideline for Filing the Standard Contract for Outbound Transfer of Personal Information* 网信办发布《个人信息出境标准合同备案指南》

个人信息处理者通过与境外接收方订立个人信息出境标准合同（“标准合同”）的方式向境外提供个人信息，是《中华人民共和国个人信息保护法》规定的个人信息出境的合规途径之一，也是程序相对便捷的路径。作为配套规则，自2023年6月1日起正式施行的《个人信息出境标准合同办法》要求相关个人信息处理者应当在标准合同生效之日起10个工作日内向所在地国家互联网信息办公室（“网信办”）省级部门备案。为进一步落实上述规定、为标准合同备案提供具体指引，网信办于2023年5月30日发布了《个人信息出境标准合同备案指南（第一版）》（“备案指南”）。

一方面，备案指南规定的备案范围（即通过订立标准合同的方式向境外提供个人信息应当符合的条件）、备案时间和个人信息出境行为的具体情形，重申了《个人信息出境标准合同办法》以及《数据出境安全评估办法》中的相关规定；另一方面，备案指南对标准合同备案的方式、时限、流程、所需材料、整改期等方面进行了具体说明，并提供了主要备案材料（其中包括标准合同、个人信息保护影响评估报告）的模板，为个人信息处理者进行标准合同备案提供了较为明确的实操指引。但值得注意的是，备案指南中尚有一些问题，例如：省级网信部门是否会对备案材料进行实质审查、备案未通过的责任后果、以及关联公司是否需要分别在各自省份网信部门办理备案；以上问题有待网信办等监管机构通过监管实践或后续规则进一步澄清。

As one of the compliant channels for outbound personal information transfer under the *Personal Information Protection Law of the People's Republic of China*, executing a Standard Contract for the Outbound Transfer of Personal Information (the "Standard Contract") offers a relatively streamlined process for providing personal information abroad. As a supporting rule, the *Measures on the Standard Contract for Outbound Transfer of Personal Information* (the "Standard Contract Measures"), which officially came into effect on June 1, 2023, require the relevant personal information handlers to file a record with the provincial-level counterparty of the Cyberspace Administration of China (the "CAC") within 10 working days from the effective date of the standard contract. To further implement and provide specific guidance on the record-filing requirement, the CAC released the *Guideline for Filing the Standard Contract for Outbound Transfer of Personal Information (First Edition)* (the "Guideline") on May 30, 2023.

On the one hand, the Guideline specifies the scope of the application for record-filing (i.e., the conditions that should be met when providing personal information overseas through executing standard contracts), the timing of record-filing, and the definition of the outbound transfer, reiterating the relevant provisions in the Standard Contract Measures and the *Security Assessment Measures for Outbound Data Transfers*. On the other hand, the Guideline details the methods, deadlines, procedures, required materials, and rectification periods for filing standard contracts, and provides templates for main filing materials, including the standard contract and the personal information protection impact assessment report. This offers more explicit practical guidance for personal information handlers to fulfill their filing obligations. However, it should be noted that there are still some issues in the Guideline, such as whether the provincial CAC will conduct a substantive review of the filing materials, the consequences of unsuccessful filing, and whether affiliated companies in different provinces need to separately file with their respective provincial CAC. These issues require further clarification through regulatory practice or subsequent rules by CAC and other regulatory agencies.

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