



Han Kun Newsletter

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1. A New Era for Regulatory Margins for Derivatives Transactions

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Overview and background

Following the economic and financial crisis in 2007, in view of the significant weakness in the resiliency of banks and other market participants to financial and economic shocks, in particular from over-the-counter (OTC) derivatives transactions, the Group of Twenty (G20) agreed on the necessity of improved transparency in the OTC derivatives markets and further regulation of OTC derivatives, and initiated a reform programme in 2009 to reduce the systemic risk from OTC derivatives which comprise of the following four elements:

- All standardised OTC derivatives should be traded on exchanges or electronic platforms, where appropriate.
- All standardised OTC derivatives should be cleared through central counterparties (CCPs).
- OTC derivatives contracts should be reported to trade repositories.
- Non-centrally cleared derivatives contracts should be subject to higher capital requirements.

In 2011, the G20 agreed to add margin requirements on non-centrally cleared derivatives to the reform programme, and the Basel Committee on Banking Supervision (BCBS) and the International Organization of Securities Commissions (IOSCO) were called upon to develop consistent global standards for these margin requirements. After several rounds of consultations and revisions, the final margining framework for non-centrally cleared derivatives set out in the *Margin Requirements for Non-centrally Cleared Derivatives* (《非集中清算衍生品保证金要求》) (“**Global Margining Framework**”) were released by BCBS and IOSCO on 4 April 2020.

To implement the Global Margining Framework in China, the National Financial Regulatory Administration (NFRA) released the *Administrative Measures on Margins for Non-centrally Cleared Derivatives Transactions of Financial Institutions* (《金融机构非集中清算衍生品交易保证金管理办法》) (“**NFRA Margin Rules**”) on 6 January 2025, which will come into effect on 1 January 2026.

We set out below the key requirements under the NFRA Margin Rules and potential implications for Covered Entities (as defined below) and their counterparties, also taking into consideration the comparison between the NFRA Margin Rules and the Global Margining Framework.

Key requirements under the NFRA Margin Rules

I. IM vs VM

The NFRA Margin Rules establish a comprehensive framework for initial margin (IM) and variation margin (VM), which is generally consistent with the requirements under the Global Margining Framework. We have prepared a summary of key regulatory requirements around IM and VM with

reference articles under the NFRA Margin Rules in the table below.

Item and Ref. article	IM	VM
Purpose	<p>IM protects the trade parties from the potential future exposure that could arise from future changes in the mark-to-market value of the contract during the time it takes to close out and replace the position in the event that one or more counterparties default. The amount of IM reflects the size of the potential future exposure. It depends on a variety of factors, including how often the contract is revalued and VM exchanged, the volatility of the underlying instrument, and the expected duration of the contract closeout and replacement period, and can change over time, particularly where it is calculated on a portfolio basis and transactions are added to or removed from the portfolio on a continuous basis.</p>	<p>VM protects the trade parties from the current exposure that has already been incurred by one of the parties from changes in the mark-to-market value of the contract after the transaction has been executed. The amount of VM reflects the size of this current exposure. It depends on the mark-to-market value of the derivatives at any point in time and can therefore change over time.</p>
Calculation frequency (Art. 12, 13)	<p>IM shall be calculated based on the netting set at the end of a business day, and shall be calculated at least every 10 days and be recalculated in the event of a change in the netting set, including, but not limited to, the initiation of a new transaction, the termination of an existing transaction, or the expiration of an existing transaction in such netting set.</p>	<p>VM shall be calculated on at least daily basis and based on the netting set at the end of a business day.</p>
<p>While the NFRA Margin Rules do not provide for the definition of netting set, Covered Entities may take reference to the <i>Rules on the Measurement of Credit Risk-weighted Assets of Counterparties</i>, Annex 9 to the <i>Administrative Measures for the Capital of Commercial Banks</i> (《商业银行资本管理办法》附件九《交易对手信用风险加权资产计量规则》), where the netting set shall refer to the collection of all transactions between a commercial bank and a single counterparty under the same valid netting agreement, e.g., ISDA Master Agreement, NAFMII Master Agreement, or SAC Master Agreement.</p>		
Timing of margin call (Art. 12, 13)	<p>A margin call notice shall be issued by close of business (COB) on the next business day following the valuation date, with the margin exchange completed by COB on the second business day following the issuance of the notice.</p>	
Margin exchange (Art. 12, 13)	<p>IM must be exchanged by transacting parties on a gross basis and there should be no offsetting of IM exchanged between transacting parties.</p>	<p>VM is exchanged by transacting parties on a net basis and shall be provided by the estimated loss-making party to the estimated gain-making party.</p>

Item and Ref. article	IM	VM
<p>Methodologies for margin calculation (Art. 14, 15, 26)</p>	<p>The required amount of IM may be calculated by reference to either (x) a standardised margin schedule (标准法), which is set forth in Annex 1 to the NFRA Margin Rules and consistent with the calculation methodology under the Global Margining Framework; or (y) a quantitative portfolio margin model (模型法), the setting and governance requirements of which are set forth in Annex 2 to the NFRA Margin Rules. When IM is calculated by reference to a quantitative portfolio margin model, such model must be approved by NFRA or its local office.</p> <p>Covered Entities under the NFRA Margin Rules may apply different methodologies for IM calculation for different asset classes, but the methodology must be consistent for the same asset class within the same netting set, and they are not allowed to switch between model- and schedule- based margin calculations in an effort to “cherry pick” the most favourable IM terms.</p> <p>Transacting parties shall agree on the methodology before the onset of the transaction.</p>	<p>There is no pre-determined methodology for VM calculation. Transacting parties shall agree on the methodology before the onset of the transaction.</p>
<p>Threshold (Art. 16)</p>	<p>No more than RMB 400 million (or its equivalent in foreign currency). The IM actually exchanged between transacting parties should subtract the threshold amount as agreed by them. The Global Margining Framework provides a threshold amount of no more than €50 million.</p> <p>The threshold shall be applied at the level of the consolidated group to which the threshold is being extended and the consolidated group which is extending the threshold. It is yet to be clarified by NFRA on (x) how the “consolidated group” should be interpreted, in particular for foreign-funded banks in China, whether the consolidated group should take into account their parents and affiliates in other jurisdictions; and (y) how asset management products should be consolidated.</p> <p>Under the Global Margining Framework, the consolidated group should extend to parents and affiliates across all jurisdictions, and asset management products managed by an investment advisor/manager shall be considered distinct entities that are treated separately when applying the</p>	<p>Zero threshold, i.e., all Covered Entities that engage in non-centrally cleared derivatives must exchange, on a bilateral basis, the full amount of VM on a regular basis.</p>

Item and Ref. article	IM	VM
	threshold as long as the products are not collateralised by or are otherwise guaranteed or supported by other products or the investment advisor/manager in the event of product insolvency or bankruptcy.	
Minimum transfer amount (Art. 16)	No more than RMB 4 million, which may be allocated between IM and VM. Only when the transfer amount required from the transferor exceeds the minimum transfer amount as agreed between the transferor and transferee, will the transferor be obliged to transfer such transfer amount to the transferee. The Global Margining Framework provides a minimum transfer amount of no more than €500,000.	

II. Scope of Covered Entities

The Global Margining Framework provides that non-centrally cleared derivatives transactions between two covered entities are governed by the margin requirements thereunder, and covered entities include all financial firms and systemically important non-financial firms; central banks, sovereigns, 11 multilateral development banks, the Bank for International Settlements, and non-systemic non-financial firms are not covered entities.

However, the NFRA Margin Rules shall only govern the non-centrally cleared derivatives to which at least one counterparty is one of the following NFRA regulated financial institutions or products (each a “**Covered Entity**” and collectively the “**Covered Entities**”):

1. Banking financial institutions, which shall include legally established commercial banks, urban and rural credit cooperatives, policy banks, and other financial institutions that absorb public deposits according to Article 2 of the *Interim Measures for the Administration of Derivatives Trading by Banking Financial Institutions* (《银行业金融机构衍生产品交易业务管理暂行办法》) (“**Interim Measures**”). Foreign bank branches and subsidiary banks are included within the scope of banking financial institutions, thus are also Covered Entities under the NFRA Margin Rules;
2. Insurance financial institutions, which shall include insurance groups (holding companies), insurance companies, and insurance asset management companies, according to Article 2 of the *Measures for the Participation of Insurance Funds in Financial Derivatives Trading* (《保险资金参与金融衍生产品交易办法》);
3. Financial holding companies approved by People's Bank of China (**PBoC**); and
4. Asset management products issued by the entities listed in 1 to 3 above.

Notably, the NFRA Margin Rules do not apply to non-centrally cleared derivatives between non-NFRA regulated financial institutions (i.e., financial institutions regulated by the China Securities Regulatory Commission (**CSRC**) such as securities firms, futures firms, mutual fund managers, etc., or their managed asset management products) and/or non-financial institutions.

III. Coverage of transactions subject to the margin requirements and exemptions

The Global Margining Framework provides that, except for physically settled FX forwards and swaps, the margin requirements shall apply to all non-centrally cleared derivatives, provided that:

1. The BCBS and IOSCO recognize that VM requirement for physically settled FX forwards and swaps is a common and established practice among significant market participants, and helps in limiting the build-up of systemic risk;
2. IM requirements for cross-currency swaps do not apply to the fixed physically settled FX transactions associated with the exchange of principal of cross-currency swaps; and
3. Derivatives for which a firm faces no (i.e. zero) counterparty risk require no IM to be collected and may be excluded from the IM calculation.

The NFRA Margin Rules have also incorporated the above exemptions, and all non-centrally cleared derivatives to which at least one counterparty is a Covered Entity shall be subject to the margin requirements (including both IM and VM requirements) under the NFRA Margin Rules, provided however the following exemptions shall apply:

1. Physical settlement

Physically settled FX forwards and swaps, and physically settled gold forwards and swaps may not apply the IM requirements, and the exchange of fixed principal of physically settled cross-currency swaps may be excluded from the IM calculation.

2. No counterparty risk

Derivatives for which a firm faces zero counterparty risk may be excluded from the IM calculation, e.g., an option writer faces no counterparty risk in front of the option purchaser so long as the option premium has been paid in full by the option purchaser, while from the option purchaser's perspective, the option purchaser still faces counterparty risk in front of the option writer, so the option writer and the option purchase shall implement different IM calculation for the same option transaction.

3. Counterparty not being a Covered Entity

For non-centrally cleared derivatives between a Covered Entity and a non-Covered Entity, the Covered Entity is only obliged to collect IM and VM from the counterparty, but is not obliged to post IM and VM to the counterparty.

4. AANA below threshold

■ Exemption of IM requirements for any Covered Entity and its counterparty

Subject to the phase-in implementation of the IM requirements discussed in Section 4 below, any Covered Entity and its counterparty will not be subject to the IM requirements if such Covered Entity and its counterparty, each of which belongs to a group whose month-end aggregate average notional amount ("AANA") of non-centrally cleared derivatives for March, April, and May of the most recent year does not reach the relevant threshold.

■ Exemption of both IM and VM requirements for any Covered Entity transacting with non-financial institutions

Any Covered Entity will not be subject to the IM or VM requirements if its non-financial institution counterparty belongs to a group whose month-end AANA of non-centrally cleared derivatives for March, April, and May of the most recent year does not reach RMB60 billion.

5. Transactions for hedging purpose

■ Transacting with non-financial institution counterparty

Any Covered Entity and its non-financial institution counterparty can be exempted from the IM and VM requirements where the non-centrally cleared derivatives between them are (x) compatible with the risk-tolerance capacity of the non-financial institution counterparty and (y) carried out with genuine risk-hedging needs.

In practice, as required under applicable laws, e.g., Article 45 of the Interim Measures, commercial banks are required to carry out derivatives trading with clients that have actual needs and transaction backgrounds, and the derivatives trading must be compatible with the clients' risk-tolerance capabilities, therefore commercial banks should be able to rely on this exemption for their derivatives trading with corporate clients, regardless of the AANA discussed in subparagraph (4) above.

That said, it is yet to be clarified by NFRA on the scope of the non-financial institutions mentioned above, in particular whether private fund managers would be included. For private funds managed by private fund managers, they are generally permitted to trade derivatives for either risk hedging purpose or asset allocation purpose, thus whether private fund managers can rely on this exemption would be uncertain.

■ Transacting with finance company of a corporate group

Any non-centrally cleared derivatives carried out by a finance company of a corporate group on behalf of the group and group members with genuine risk-hedging needs shall be exempted from IM and VM requirements.

6. Sovereign entities

The IM and VM requirements are exempted for non-centrally cleared derivatives between Covered Entities and central banks, government organisations, public sector entities, multilateral development banks, the Bank for International Settlements, or China's policy banks; and

7. Intragroup trading

The non-centrally cleared derivatives between entities that are included in the same consolidated financial statements of a group shall be exempted from both IM and VM requirements.

IV. Phased-in implementation of margin requirements

In alignment with the Global Margining Framework, the margin requirements under the NFRA Margin Rules are also implemented on a phased-in basis so that the systemic risk reductions and incentive benefits are appropriately balanced against the liquidity, operational and transition costs associated with implementing the margin requirements.

Specifically, the VM requirements will be put into practice from 1 September 2026, and the IM requirements will be phased in over 3 stages as follows:

- From 1 September 2027: any Covered Entity and its counterparty, each of which belonging to a group whose month-end AANA of non-centrally cleared derivatives for March, April, and May of the most recent year exceeds RMB500 billion, will be subject to the IM requirements;
- From 1 September 2028: any Covered Entity and its counterparty, each of which belonging to a group whose month-end AANA of non-centrally cleared derivatives for March, April, and May of the most recent year exceeds RMB300 billion, will be subject to the IM requirements; and
- From 1 September 2029: any Covered Entity and its counterparty, each of which belonging to a group whose month-end AANA of non-centrally cleared derivatives for March, April, and May of the most recent year exceeds RMB60 billion, will be subject to the IM requirements.

After each relevant implementation date, where the AANA falls below relevant threshold above, the IM requirements shall cease to apply from the 1 September of that year, until the AANA reaches relevant threshold again then the IM requirements shall resume to apply.

When calculating the AANA, —

- All non-centrally cleared derivatives should be included, including the physically settled FX forwards and swaps, and physically settled gold forwards and swaps; and
- Similar with the application of threshold at the group level as discussed in Section 1 above, it is yet to be clarified by NFRA how to interpret the scope of “group” for the purpose of calculating the AANA, e.g., whether the notional amounts of non-centrally cleared derivatives to which the parents and offshore affiliates of foreign-funded Covered Entities in China are parties should be included. It is notable that under the Global Margining Framework, the group shall comprise group members across all jurisdictions.

V. Transitional arrangement for new transactions and existing transactions

Subject to the phase-in implementation of the margin requirements discussed in Section 4 above, the IM requirements shall apply to new transactions on or after the phased implementation date of IM requirements, and the VM requirement shall apply to new transactions on or after 1 September 2026.

NFRA further clarifies that the existing transactions, and confirmation or non-substantial amendments to existing transactions do not qualify as a new transaction, and any substantial amendments to existing transactions or any amendment that is intended to extend an existing transaction for the purpose of avoiding margin requirements will be treated as a new transaction. For existing transactions, parties thereto may also, within their discretion, apply margin requirements.

VI. Eligible collateral

According to Article 18 of the NFRA Margin Rules, eligible collateral to satisfy the IM and VM requirements include:

1. Cash;
2. Government bonds issued by China's Ministry of Finance, bills issued by the PBoC, and bonds and bills issued by China's policy banks;
3. Bonds issued by China's provincial people's governments (including autonomous regions and direct-administered municipalities) and cities under separate state planning;
4. High-quality bonds issued by other national or regional governments and their central banks, sovereign-equivalent public sector entities, the Bank for International Settlements, the International Monetary Fund, the European Central Bank, the European Union, the European Stability Mechanism and the European Financial Stability Mechanism, and multilateral development banks;
5. High-quality corporate credit bonds;
6. High-quality financial bonds;
7. Gold; and
8. Other eligible collateral recognized by NFRA.

Compared to the Global Margining Framework, equities included in major stock indices are not enlisted as eligible collateral, even though the Covered Entities and their counterparties may seek separate approval from NFRA for using other types of assets as eligible collateral. The NFRA Margin Rules further require Covered Entities to prudently evaluate the risk mitigating effect of collateral to ensure compliance with their internal risk management requirements when using other types of assets as collateral.

VII. Management of provided collateral and margins

The NFRA Margin Rules provide several management requirements in terms of the provided collateral and margins as follows:

1. Application of haircut

Consistent with the Global Margining Framework, the collected collateral, should, after accounting for an appropriate haircut, be able to hold their value in a time of financial stress. Accordingly, Article 19 of the NFRA Margin Rules requires Covered Entities to use either (x) the standardised haircuts set forth in Annex 3 to the NFRA Margin Rules; or (y) internal or third-party haircut calculation models, which must be approved by NFRA or its local office, to calculate the value of collected collateral. The choice of haircut calculation should be consistent across the same type of collateral.

2. Management of collateral risk

■ FX risk

The Global Margining Framework requires that, in addition to having good liquidity, eligible collateral should not be exposed to excessive credit, market and FX risk. To address the potential excessive FX risk, Article 20 of the NFRA Margin Rules requires Covered Entities to apply extra FX haircut in the case of differences between the currency of the collateral asset and the termination currency of

relevant transactions or the base currency in the relevant collateral document.

■ **Concentration risk**

The Global Margining Framework provides that accepted collateral should be reasonably diversified. Article 20 of the NFRA Margin Rules thus requires Covered Entities to ensure that collected collateral is not overly concentrated in the same issuer, same type of issuers or same asset class, and to have policies in place to manage the concentration risk of non-cash collateral. High-quality bonds issued by sovereign and sovereign-equivalent public sector entities, the Bank for International Settlements, the International Monetary Fund, the European Central Bank, the European Union, the European Stability Mechanism and the European Financial Stability Mechanism, or multilateral development banks are exempted.

■ **Wrong way risk (错向风险)**

Consistent with the Global Margining Framework, Article 20 of the NFRA Margin Rules requires Covered Entities to avoid using collateral as margin that exhibit a significant correlation with the creditworthiness of the counterparty or the value of the underlying non-centrally cleared derivatives portfolio in such a way that would undermine the effectiveness of the protection offered by the margin collected. Specifically, marketable securities issued by the counterparty or by institutions the financial statements of which are consolidated into the same group as the counterparty shall not be used as margin.

3. Substitution of collateral

Article 21 of the NFRA Margin Rules permits the substitution of collateral, provided that the alternative collateral must meet the conditions for eligible collateral, and the value of the alternative collateral, after the application of haircuts, must be sufficient to meet the margin requirement.

4. Segregation of provided IM

The Global Margining Framework provides that IM collected should be held in such a way as to ensure that (i) the margin collected is immediately available to the collecting party in the event of the counterparty's default, and (ii) the collected margin must be subject to arrangements that protect the posting party to the extent possible under applicable law in the event that the collecting party enters bankruptcy. Accordingly, to achieve the effect of bankruptcy remoteness of the IM, Article 22 of the NFRA Margin Rules requires that, collateral used as IM shall be custodied by a qualified third-party custodian, and shall be effectively segregated from the proprietary assets of the parties to the transaction, proprietary assets of the third-party custodian and the collateral of other counterparties under their management.

In practice, to ensure the bankruptcy remoteness of the IM collected and to ensure the immediate availability of the IM, the IM will be exchanged by way of creating security interest (as opposed to absolute title transfer).

There is no segregation requirement for the VM, so the VM collected can either be managed by the parties to the transaction themselves or be entrusted to a qualified third-party custodian. Accordingly,

in practice, the VM are normally exchanged on a title transfer basis.

5. Rehypothecation, repledge and reuse of provided margins

Article 25 of the NFRA Margin Rules provides that the provided IM shall, in principle, not be rehypothecated, repledged or reused, and the provided VM can be rehypothecated, repledged or reused.

NFRA does not provide further guidance on what would constitute an exception to the principle of prohibition of rehypothecation, repledge and reuse of provided IM. The Global Margining Framework provides that cash and non-cash collateral collected as IM from a customer may be re-hypothecated, re-pledged or re-used to a third party only for purposes of hedging the IM collector's derivatives position arising out of transactions with customers for which IM was collected and it must be subject to conditions that protect the customer's rights in the collateral, to the extent permitted by applicable national law. In this context, customers should only include "buy-side" financial firms as well as non-financial entities, but shall not include entities that regularly hold themselves out as making a market in derivatives, routinely quote bid and offer prices on derivative contracts and routinely respond to requests for bid or offer prices on derivative contracts. We trust NFRA will permit similar exception.

VIII. Report on disputes over margins

Article 28 of the NFRA Margin Rules provides a new regulatory requirement that Covered Entities should record the duration of disputes over margins, the counterparties and the disputed amount. Where a margin dispute with a single counterparty remains unresolved for more than 15 business days, and the disputed amount exceeds RMB 100 million (or its equivalent in other currencies), Covered Entities should clarify the reporting line through internal management rules.

IX. Cross-border applicability

NFRA appreciates that different jurisdictions have their own regulatory margin requirements for non-centrally cleared derivatives, and a Covered Entity could be subject to different set of regulatory margin regimes at the same time due to the counterparty to the cross-border derivatives transactions or the home jurisdiction of its parent. To address potential conflicts, Articles 29 and 30 of the NFRA Margin Rules provides the followings:

1. Application of equivalent or more prudent margin requirements

Where a Covered Entity conducts cross-border non-centrally cleared derivatives and is subject to margin requirements of a foreign jurisdiction, such Covered Entity may choose to apply the margin requirements of that foreign jurisdiction, provided that such margin requirements are consistent with the Basel margin requirements and are equivalent to, or are more prudent than those under the NFRA Margin Rules.

2. Foreign branches of Covered Entities

The foreign branches of Covered Entities may apply the margin requirements in the jurisdiction where they are located when conducting non-centrally cleared derivatives.

3. Foreign institutions transacting in China

Foreign institutions conducting non-centrally cleared derivatives transactions directly in the domestic financial market in China shall comply with the relevant requirements for onshore transactions.

4. No legally enforceable netting agreement or collateral agreement

If netting agreements or collateral agreements are not legally enforceable in the jurisdiction of foreign institution counterparties with which a Covered Entity conducts non-centrally cleared derivatives transactions, such Covered Entity may not exchange margins with such foreign institution counterparties, and the notional amount of non-centrally cleared and uncollateralized derivatives transactions between such Covered Entity and all the counterparties in that jurisdiction should not exceed 2.5% of the total outstanding notional amount of derivatives transactions carried out by the group to which such Covered Entity belongs.

X. Documentation

The NFRA Margin Rules do not specify the documentations that should be used to document the exchange of margins. On 14 September 2024, the National Association of Financial Market Institutional Investors (NAFMII) released the consultation draft of the *Title Transfer Type Performance Assurance Document (Variation Margin) for Financial Derivatives Transactions in CIBM* (《中国银行间市场金融衍生产品交易转让式履约保障文件(变动保证金)征求意见稿》) (“VM PAD”) to solicit comments among a small group of market participants. The VM PAD is equivalent to the VM CSA in the context of ISDA documentations, and would constitute a confirmation under the NAFMII Master Agreement, and the transaction contemplated under the VM PAD would constitute a transaction under the NAFMII Master Agreement as well, which will be included in the scope of close-out netting regime applicable to all transactions under the single agreement. Upon the finalization of the VM PAD, Covered Entities may use the VM PAD to document the exchange of VM with their counterparties.

NAFMII also mentioned in the drafting notes to the VM PAD that they will release the documents for IM exchange at a later stage.

Outlook

The promulgation of the NFRA Margin Rules marks a significant milestone in the implementation of the regulatory margin framework in China, and will help align the China market with international practice.

However, there are still several uncertainties around the NFRA Margin Rules that need further clarification by NFRA, such as the definition and scope of “group”, “non-financial institution”, how the asset management products should be treated for the purpose of IM and VM requirements applicable at the group level, etc. Also, the regulatory framework for non-NFRA regulated financial institutions is pending CSRC’s further action, and it is yet to be seen how these two regulatory frameworks would interact with each other.

Han Kun will closely monitor any progress in the regulatory margin regimes and keep clients posted.

2. Six Key Insights into China Biotech's NewCo Model

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In the age of globalization, Chinese pharmaceutical companies are at the forefront of innovation and collaboration, seizing unprecedented development opportunities. Meanwhile, overseas investors and pharmaceutical companies are also keen to capture investment and development opportunities, and actively looking for new growth areas in the pharmaceutical industry. Against this backdrop, the Spin off-NewCo model (commonly referred to as “SON” or “NewCo” model), which gained popularity in 2024, has effectively met the needs of all parties involved. This model has set a new trend for Chinese companies expanding internationally, empowering many of them to secure a first-mover advantage in global competition (for practical insights into the “SON” model, please refer to our analysis article: [*“Insights into China Biotech’s New Approach: Spin-off-NewCo Model”*](#)).

Having advised many NewCo projects, we have gained a deep understanding of their strategic value, commercial opportunities, and associated risk. This article draws on our team’s practical experience and provides a concise overview of recent developments in the NewCo model. We analyze key practical aspects of the NewCo model, including strategic considerations for Spin-off, comparisons with traditional out-licensing deals, non-traditional NewCo model, and other factors to consider when establishing a NewCo, aiming to offer valuable insights and encourage discussion within the industry.

Strategic decisions in spin-off and securing a “first-mover advantage”

Spin-off is a critical step in implementing the NewCo model. In most projects, the Spin-off process begins after external investors become involved. In such cases, external investors with a strong interest in specific pipeline assets often require the licensor (“Licensor”) to fully license the relevant pipeline assets or rights to a NewCo established by the investors or jointly by both parties. This approach aims to maximize resource advantages and drive the development and commercialization of these pipeline assets effectively.

Recently, we have observed another type of Spin-off strategy, led by the Licensor through internal restructuring within its corporate group. Some biotech companies strategically arrange their internal pipeline layouts, proactively establish NewCos, and allocate relevant pipeline assets in advance. This approach enables them to take greater initiative in subsequent market expansion and international collaboration, maintain effective control over key assets and optimize long-term returns.

These two Spin-off strategies demonstrate the first-mover advantage within the NewCo model, which is leveraged by the leading party in the Spin-off. The choice of a specific Spin-off strategy further depends on the Licensor or investor who makes informed decisions based on their market positioning, resource allocation needs, and risk tolerance.

¹ Jingjing XU have contributions to this article.

License model vs. NewCo model: comparisons of revenue pathways and control

Some Licensors, possessing high-quality assets that have made development progresses, may face a choice between the traditional License model and the NewCo model.

In the short term, the traditional License model generates revenue from pipelines more quickly than the NewCo model. Under the traditional License model, the Licensee typically attracts the Licensor by offering substantial upfront payments. This approach enables the Licensor to secure significant income in the short term and alleviate its financial pressure, making the model an appealing option. In contrast, the NewCo model may provide less initial revenue to the Licensor, as the monetization of its assets or rights heavily relies on continued pipeline development and subsequent advancements. As a result, short-term cash flow is relatively slower. However, by effectively integrating resources through the NewCo model, Licensors may achieve significantly higher returns from equity in subsequent license-out transactions, mergers and acquisitions, or public offerings.

For Licensors, the NewCo model offers relative advantages over traditional License model providing greater control over pipeline products and promoting their development and commercialization. In the traditional License model, the Licensee typically holds control over the development of licensed products. Given the potential presence for competing pipelines under development, the Licensee's strategic decisions may introduce uncertainties about further development and commercialization of the licensed products. In the NewCo model, however, the Licensor assumes dual roles as both a shareholder of the NewCo and the grantor of the license. This structure provides the Licensor with greater control over pipeline development compared to the traditional License model. Such control not only facilitates continued product development but also provides Licensor with greater potential for revenue-sharing in the Licensee's future benefits. Particularly after the commercialization of the pipeline, the Licensor stands to benefit not only from milestone payments tied to sales performance but also from long-term equity dividends and appreciation.

In terms of clause design, the focus of the traditional License model and the NewCo model differs significantly. Given the strategic priorities and unique considerations of each party, key provisions – such as diligence obligations, non-compete clauses, termination clauses, and exclusivity clauses – often vary substantially to address specific needs. Therefore, we recommend that companies or investors seek assistance from industry experts, including experienced transactional attorneys and tax professionals, when crafting such agreements. By aligning contractual terms with strategic objectives and expected outcomes, parties can balance interests effectively and mitigate potential risks.

Breaking stereotypes about the NewCo model: Chinese NewCo and its global expansion

Pharmaceutical companies often face numerous challenges in their globalization process, such as difficulties in financing, fluctuations in cross-border investment regulations, and restrictions on foreign investment and regulatory compliance. The NewCo model inherently offers advantages in addressing these challenges. Specifically, within the commonly used framework of “Dollar Funds + Chinese Assets + U.S. Teams”, Delaware in the United States is typically the preferred location for establishing a NewCo

due to its favorable tax policies, flexible corporate laws, and investor-friendly protection mechanisms.

However, with the evolution of transactional practices, the NewCo model has become increasingly diversified in its applications. Given its inherent capabilities – such as streamlining pipeline products, spinning off assets, and reducing financing challenges – setting up a NewCo in China has emerged as a new option in transactions where biotech companies act as Licensors and collaborate with Chinese domestic investors or enterprises. This approach not only reduces communication and transaction costs but also significantly shortens project timelines. We have had the experience of participating in projects involving the establishment of NewCos in China, gaining extensive practical experience with this emerging approach.

We would like to highlight that the globalization of a Chinese NewCo does not conflict with the traditional overseas NewCo model; they can even proceed concurrently. Furthermore, Chinese NewCo can leverage their inherent advantages to develop Chinese and overseas rights in parallel, creating a “NewCo + NewCo” model. This approach optimizes market expansion mechanisms and facilitates a more comprehensive global strategic layout.

Comparison between traditional and non-traditional NewCo models: the rise of non-traditional NewCo model

In recent years, driven by the evolving landscape of innovative drug development and financing needs, the traditional NewCo model has gradually given rise to more flexible and innovative non-traditional NewCo model, providing the market with diversified solutions. Under the traditional model, funds typically flow with the NewCo paying license fees to the Licensor, with investors participating in project returns indirectly through equity ownership in the NewCo. However, as the NewCo model continues to evolve, new approaches to fund allocation have emerged to meet varying commercial demands.

The key of the non-traditional NewCo model lies in designing fund flows and equity arrangements flexibly based on the specific project requirements. For instance, we assisted in a NewCo transaction where the NewCo was established under the leadership of the Licensor. In this case, investors made direct payments to the Licensor or its affiliated entities in exchange for the option right to acquire the NewCo in the future. This design not only enabled the Licensor to secure funding in the early stages and promote pipeline development but also provided investors with a clear mechanism to lock in returns upon the project reaching key milestones. Compared with the traditional NewCo model, this structure allows investors to ensure greater certainty by committing more significant financial resources, creating mutually beneficial cooperation conditions for both parties.

The rise of the non-traditional NewCo model demonstrates that the NewCo model is not merely a financing tool but also a strategic approach to resource integration. Looking ahead, companies can develop and choose suitable models flexibly based on their own needs and market conditions, aiming to maximize pipeline value and achieve breakthroughs in international objectives.

Core competitiveness of the NewCo model

The essence of the NewCo model lies in integrating resources from all parties to advance asset

development and commercialization with maximum efficiency. Currently, the NewCo model demonstrates strong competitiveness in the global market, driven primarily by investors familiar with overseas markets and management teams experienced in overseas regulatory approvals, clinical trials, and product launches. Leveraging overseas funding and international teams, combined with China's innovative assets, the NewCo model has established a critical position in global drug development and commercialization.

Moreover, in recent years, an increasing number of local teams with international experience have begun to emerge, proving that the success of the NewCo model is not exclusive to foreign investors or teams. With the support of internationally experienced professionals, well-capitalized Chinese investors can achieve significant breakthroughs through the NewCo model. As long as they possess core teams familiar with overseas market regulations, regulatory processes, and product launch operations, Chinese investors can build efficient NewCo structures and serve as a key driver in the globalization of domestic innovative assets.

Currently, the U.S. and other western markets remain the core stages for global pharmaceutical commercialization. Nonetheless, Chinese investors do not need to be confined to traditional paths. By leveraging their capital advantages and recruiting professionals with international backgrounds, they can break through existing paradigms and explore the RMB-dominated NewCo model. This development not only facilitates the internationalization of Chinese assets but also creates a new model of "Chinese capital + international teams", injecting fresh vitality and confidence into the growth of NewCo. We firmly believe that with sufficient funding and a robust reserve of international talent, the Chinese NewCo model will occupy a more significant position in the global pharmaceutical landscape in the future.

The impact of geopolitics on the NewCo model

Geopolitical factors are profoundly influencing the globalization of the NewCo model. Multinational corporations are increasingly cautious in their collaboration with Chinese companies, citing complexities in due diligence and the lack of international credibility as key concerns. As a result, many companies are leaning toward partnerships with overseas entities, such as U.S.-based companies. This trend underscores the global market's emphasis on transaction transparency and compliance, posing new challenges for Chinese pharmaceutical companies (Licensors) in their global collaboration strategies.

To address these challenges, some Chinese companies have begun to adjust their global intellectual property (IP) strategies. For example, they are optimizing group IP arrangements in advance based on the NewCo's location (e.g., Singapore or the U.S.) and considering tax implications. Such adjustments not only enhance the convenience of cross-border cooperation but also mitigate uncertainties arising from geopolitical shifts. Additionally, with China's continuous advancement in high-level, high-quality openness, the cross-border flow of patents and technologies has been significantly invigorated, reducing barriers to pipeline Spin-offs and cross-border technical collaborations in biopharma. This creates new opportunities for Chinese pharmaceutical Licensors to optimize their IP layouts and expand into global markets.

Looking ahead, we recommend that Chinese companies incorporate geopolitical and tax factors into their

IP strategy planning and develop specialized global strategies to enhance their international competitiveness. By optimizing the allocation of domestic and overseas resources, Chinese innovative pharmaceutical companies can participate more smoothly in global transactions. Furthermore, leveraging the NewCo model can facilitate more efficient internationalization of innovative assets, ultimately maximizing long-term commercial value.

Conclusion

As the global pharmaceutical market continues to evolve, the NewCo model, as a flexible and forward-looking strategic choice, is garnering increasing attention from the industry. Whether through the steady progression of traditional models or the flexible innovation of non-traditional approaches, the NewCo model provides Chinese pharmaceutical companies and external investors with expanded opportunities in the global market. In the face of geopolitical complexities, cross-border regulatory challenges, and dynamic financing environments, Chinese companies and external investors must adopt a more professional perspective in planning their strategies. By integrating domestic and international resources, optimizing patent layouts, and strengthening collaboration with international teams, they can better navigate challenges and seize opportunities. We firmly believe that the NewCo model will unleash even greater innovative potential in the future, creating broader prospects for the development of innovative pharmaceuticals.

3. Navigating NFRA Compliance Measures for Foreign Funded Banks

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Overview

On 27 December 2024, the National Financial Regulatory Administration (“**NFRA**”) issued the *Measures for the Compliance Management of Financial Institutions* (《金融机构合规管理办法》)(“**Compliance Measures**”), which will take effect on 1 March 2025. Prior to that, the NFRA released the consultation draft of the Compliance Measures to solicit public comments on 16 August 2024 (“**Consultation Paper**”).

The Compliance Measures are built upon the *Guidelines on Compliance Risk Management for Commercial Banks* (《商业银行合规风险管理指引》)(“**Old Compliance Guidelines**”), and the *Administrative Measures for the Compliance Management of Insurance Companies* (《保险公司合规管理办法》), and will replace them from 1 March 2025, aiming to guide financial institutions (including commercial banks) in establishing more comprehensive and effective compliance management systems by drawing from years of market practice.

We outline below the key requirements under the Compliance Measures and their potential implications for foreign funded banks (including subsidiary banks and where applicable, foreign bank branches) in China (“**Banks**” or a “**Bank**”). Please note a one-year transition period is granted and Banks should complete their alignment with the Compliance Measures by the end of February in 2026.

Key requirements

I. Scope of application

The Compliance Measures apply to wholly foreign owned subsidiary banks and JV banks, among other banking and insurance institutions. Foreign bank branches, among other specified NFRA regulated entities, will need to comply with the Compliance Measures *mutatis mutandis* according to their industry-specific characteristics and regulatory requirements.

II. Expanding coverage

Article 3 of the Compliance Measures provides that “Compliance” for Banks refers to the compliance with such rules that govern Banks’ operations and employee conducts, including laws, administrative regulations, departmental rules, normative documents, and internal policies formulated by Banks to meet regulatory requirements.

Compared to the Old Compliance Guidelines and the Consultation Paper, the Compliance Measures remove the industry self-regulation standards out of compliance’s coverage. However, Article 6 of the Compliance Measures provides that the China Banking Association shall formulate implementing rules of the Compliance Measures and implement self-regulatory management on the compliance work of its member banks. Banks will still need to abide by those industry self-regulation standards to avoid potential disciplinary measures.

Another point worth noting is that the internal policies formulated by financial institutions to meet regulatory requirements are added into the scope of compliance obligations, which echoes NFRA's requirement for all banking and insurance financial institutions (including Banks) to timely and dynamically incorporate regulatory provisions into their internal policies under the *Notice of the China Banking and Insurance Regulatory Commission on launching the "Internal Control and Compliance Management Construction Year" Activity in the Banking and Insurance Industries* (《中国银保监会关于开展银行业保险业“内控合规管理建设年”活动的通知》). Banks will need to revisit their internal policies from time to time and ensure they properly incorporate then applicable regulatory requirements.

III. Compliance management system

1. Top-down responsibility system

The Compliance Measures assign compliance responsibilities to all levels of departments and employees within Banks, creating a comprehensive top-down responsibility system, which is detailed in the following table:

Responsible party	Compliance responsibility	Ref. articles
Board of directors (“BOD”) (including the sole director), and, if applicable, the compliance committee or other specialized committees established under the BOD	bearing ultimate responsibility for the effectiveness of compliance management. <i>Note:</i> Normally foreign bank branches only set up management committees to perform the management functions. Their parent banks will bear the ultimate compliance responsibility.	Articles 8 and 11
Senior management personnel (“SMP”)	taking responsibility for implementing compliance management objectives and assuming leadership responsibilities for business compliance in the areas they are responsible for . Among these, the Chief Compliance Officer (“CCO”) shall assume specific leadership responsibilities for the compliance management of the institutions and its employees.	Articles 8, 13, and 18
Compliance management department	taking the lead to undertake compliance management responsibilities and bearing management responsibility for compliance .	Articles 3 and 35
The principal responsible persons of all departments, branches, and financial subsidiaries at all levels subject to consolidated management (the “Subordinate Institutions”)	implementing the compliance management objectives of their respective departments or institutions at the corresponding level, and taking the primary responsibility for the compliance management of their respective departments or institutions at the corresponding level .	Article 9

Responsible party	Compliance responsibility	Ref. articles
Business and functional departments and Subordinate Institutions	bearing entity responsibilities (“主体责任” in Chinese) for compliance within such entity.	Article 35
Internal audit department	bearing supervisory responsibilities for compliance.	Article 35
All employees	complying with relevant compliance norms relating to their duty performance, actively identifying and controlling compliance risks arising from their duty performance, cooperating with Banks and regulators in conducting compliance management, and bearing responsibility for the compliance of their duty performance.	Article 36

2. Compliance management department

- (1) *Department set-up* — according to Article 3 of the Compliance Measures, Banks are free to decide whether to concentrate all compliance management functions within a single department or split into several non-conflicting departments to jointly undertake compliance management duties, provided that in the latter case, Banks shall clearly designate the leading department responsible for compliance management.
- (2) *Duties* — Article 28 of the Compliance Measures outlines the main responsibilities of the compliance management department, covering the entire process of pre-, during-, and post-event activities, including: leading the organization of compliance reviews, compliance checks, evaluations, compliance risk monitoring, and handling compliance events; formulating compliance norms; promoting the effective implementation of compliance norms etc. These duties clarify the basic workflow of compliance management.
- (3) *Reporting lines* — the compliance management department at Banks shall report to CCO. The compliance management departments at provincial-level or first-tier branches shall report to compliance officers at the same level, and any compliance management department of a Subordinate Institution shall be guided and supervised by higher-level compliance management department.

IV. Compliance personnel management system

1. CCO and compliance officers

According to Article 13 of the Old Compliance Guidelines, CCO (practically often referred to as the compliance head (“合规负责人” in Chinese) in Banks) shall be appointed by the SMP, typically the president (“行长” in Chinese). The Compliance Measures establish unified requirements for Banks to appoint CCO and compliance officers, with the specific requirements as follows:

Item	CCO	Compliance officer
Appointment	A CCO must be appointed at the head office – for foreign bank branches, before the NFRA gives any further clarification, it should be expected that a CCO must be appointed at the managing branch (“管理行” in Chinese) or the sole branch.	<i>In principle</i> , a compliance officer must be appointed at each provincial-level or first-tier branch.
Qualifications	<p>A CCO shall satisfy the following qualification requirements:</p> <ul style="list-style-type: none"> ■ bachelor’s degree or higher (the “full-time bachelor” requirement from the Consultation Paper has been removed); ■ at least 8 years of finance work experience with a minimum of 3 years of legal and compliance work experience; or at least 8 years of legal and compliance work experience with a minimum of 3 years of finance work experience, or at least 8 years of finance work experience with the legal professional qualification certificate; and ■ other conditions prescribed by NFRA. 	<p>A compliance officer shall satisfy the following qualification requirements:</p> <ul style="list-style-type: none"> ■ bachelor’s degree or higher (the “full-time bachelor” requirement from the Consultation Paper has been removed); ■ at least 6 years of finance work experience with a minimum of 3 years of legal and compliance work experience; or at least 6 years of legal and compliance work experience with a minimum of 3 years of finance work experience; or at least 6 years of finance work experience with the legal professional qualification certificate; and ■ other conditions prescribed by NFRA.
Reporting lines	CCO shall report to the chairman and the president of the Bank.	Compliance officers shall primarily report to CCO and also report to the president at the corresponding headquarter or branch where he/she works.
Appointment	The appointment of CCO shall be decided by the BOD.	There is no mandatory requirement on the decision-making body of the appointment of compliance officers. CCO is encouraged to oversee the appointment of compliance officers.
Dismissal	<p>The dismissal of CCO or compliance officers shall be based on legitimate reasons, including but not limited to:</p> <ul style="list-style-type: none"> ■ resignation by CCO or compliance officers; ■ replaced by NFRA or its local offices; or ■ proved to be incapable to fulfill duties as CCO or compliance officers, or fail to fulfill such duties diligently. 	
Dual-hatting	CCO or compliance officers may concurrently serve as a SMP in a same Bank.	

Item	CCO	Compliance officer
	Where the president of Banks concurrently holds the position of CCO or the president of the provincial-level or first-tier branches of Banks concurrently holds the position of compliance officers, the president will not need to satisfy the qualification requirements for CCO or compliance officers and obtain separate qualification approval.	
Independence	CCO or compliance officers shall not take responsibilities for managing front-office business, finance, fund operation, internal audit, or other departments that could present a conflict of interest with compliance management, except when the president concurrently holds the position of CCO or compliance officers as discussed in the section (Dual-hatting) above.	

2. Rights and obligations of CCO and compliance officers

Item		Details
Rights	Right to know and investigate	<ul style="list-style-type: none"> ■ be entitled to attend or sit in on relevant meetings and to review or copy related documents and materials as required for the performance of their duties. Banks must notify CCO in advance of convening important meetings, such as BOD meetings and operational decision-making meetings; ■ have the right to make inquiries and collect evidence from the relevant internal departments or Subordinate Institutions as required for performing their duties, to request the relevant personnel of Banks to explain the relevant issues, and to seek information from such intermediary institutions as external audit institutions and legal service institutions.
	Veto power	If CCO or compliance officers discover instances where any departments or Subordinate Institutions conceal or fail to report Major Violations and Significant Risks (as defined below), they must exercise the veto power against relevant Subordinate Institutions and relevant responsible personnel in charge during the internal compliance assessment of Banks, disqualify them from any excellence appraisal or awards, and promptly enforce internal accountability.
	Proposing accountability measures	CCO has the right to propose suggestions to the BOD, SMP, relevant departments, and Subordinate Institutions on taking measures such as salary reductions, position adjustments, or demotions against relevant responsible personnel, and urge the responsible entities and personnel to ensure timely rectifications.
Obligations	Issuance of compliance review opinions	<p>CCO shall organize compliance reviews and issue written compliance opinions for the following two matters:</p> <ul style="list-style-type: none"> ■ Banks' development strategy, significant internal regulations, important new products and important new business plans, and major decision-making matters; and

Item		Details
		<p>■ application materials or reports submitted to the NFRA or its local offices that NFRA require CCO's compliance review. Other relevant SMP shall be responsible for the authenticity, accuracy, and completeness of the basic facts and business data in such application materials or reports.</p> <p>If CCO's compliance opinions are not adopted (e.g., a new business is ultimately launched based on Banks' internal decisions or third-party opinions despite CCO's opposing views), Banks shall submit the relevant matters to the BOD for determination. Major matters shall also be promptly reported to the NFRA or its local offices.</p>
	Report of Major Violations and Significant Risks	<p>When CCO identifies Major Violations and Significant Risks involving Banks or their employees, he/she shall promptly report the same to the BOD, the chairman of the BOD, or the president, put forward his / her processing opinion, and urge corrective actions.</p> <p>If Banks themselves are involved in Major Violations and Significant Risks, they must promptly report to the NFRA or its local offices. If Banks fail to report, CCO shall, in his or her own name, directly report to the NFRA or its local offices.</p> <p>According to Article 22 of the Compliance Measures, Major Violations and Significant Risks means major violations of laws and regulations or significant potential compliance risks, mainly including a relatively large amount of fine or confiscation of a relatively large amount of illegal gains; compliance risk events, legal dispute cases, and criminal cases that cause or may cause significant property losses or significant reputation losses to Banks concerned. While NFRA does not provide further guidance on the Major Violations and Significant Risks, Banks may refer to the existing standards under other NFRA rules for now, such as over RMB5million constitutes "relatively large amount" under the <i>Measures for Administrative Penalty by the China Banking and Insurance Regulatory Commission</i> (《中国银保监会行政处罚办法》), until NFRA gives further clarification.</p>
	Actions required for other violations and risks	<p>Where CCO identifies violations and risks (other than Major Violations and Significant Risks) involving Banks or their employees, he/she shall, in accordance with Banks' internal compliance management procedures, organize and procure the relevant entity/department to promptly report, handle and make corrections.</p>

3. Compliance personnel

(1) Professional background

According to Article 38 of the Compliance Measures, the compliance management department should be mainly comprised of those personnel having education background in law or economics or finance, but there is no quantified criteria for the "mainly" referred to in this article.

Additionally, it is required that, in principle, personnel who are engaged in reviewing Banks' contracts from legal and compliance perspective for the first time, or issuing legal and compliance opinions on Banks' major events such as reform and reorganization, merger and acquisition and listing, transfer of property rights, bankruptcy reorganization, reconciliation and liquidation, shall have a legal background or have passed the legal professional qualification examination. Compared to the Consultation Paper, "in principle" is added to provide more flexibility.

(2) Compliance personnel in business departments and subordinate institutions

Article 39 requires all departments and Subordinate Institutions shall be equipped with full-time or part-time personnel engaged in compliance work that are commensurate with their business scale and risk control difficulty. Compared to the Consultation Paper, the Compliance Measures allow those departments and Subordinate Institutions having lower compliance risks to have part-time compliance personnel.

4. Evaluation of compliance personnel and remuneration system

Article 43 of the Compliance Measures requires that Banks shall formulate an evaluation and management system for CCO, compliance officers, compliance management department, and full-time compliance management personnel, and shall not adopt evaluation methods that are not conducive to compliance independence, such as the evaluation of SMP who are not in charge of the compliance management department, the evaluation of other departments, or the evaluation based on the business performance of the business department, except for the principal person in charge of Banks; compliance work that requires the joint efforts of all departments must not be used as a separate evaluation indicator for compliance management departments.

Banks shall also establish a mechanism for managing the remuneration of CCO, compliance officers and compliance management personnel, and the remuneration shall comply with following standards:

- (1) *CCO*: the annual total remuneration should generally not be lower than the average level for SMP with the same qualifications (same rank, same evaluation results).
- (2) *Compliance officers and compliance management personnel*: the annual total remuneration should generally not be lower than the average level for personnel with the same qualifications (same job type, same rank, same evaluation results).

Outlook

The Compliance Measures set a comprehensive guideline for the establishment and operation of compliance management systems within Banks. Banks will need to revisit existing compliance management systems and make necessary adjustments to fully comply with the Compliance Measure by the end of February in 2026. It also remains to be seen whether NFRA will provide window guidance on the scope of Major Violations and Significant Risks, application of the Compliance Measures to foreign bank branches. Han Kun will closely monitor the regulatory updates and assist Banks to achieve continuous compliance.

Important Announcement

This Newsletter has been prepared for clients and professional associates of Han Kun Law Offices. Whilst every effort has been made to ensure accuracy, no responsibility can be accepted for errors and omissions, however caused. The information contained in this publication should not be relied on as legal advice and should not be regarded as a substitute for detailed advice in individual cases.

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