NISHIMURA & ASAHI

First Quarter 2024
(Jan. - Mar.)

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Indonesia Authors: Jeanne Donauw and Hans Adiputra Kurniawan

1. Peer-to-peer (“P2P”) Lending

The Indonesian Financial Services Authority (*Otoritas Jasa Keuangan* – “**OJK**”) issued OJK Circular Letter No. 1/SEOJK.06/2024 to set further the implementation of Regulation No. 10/POJK.05/2022 on Information Technology-Based Collective Financing Services. This Circular Letter sets out procedures and mechanisms for submission of data on lending transactions and reporting for information technology-based collective financing service providers.

According to this Circular Letter, beginning on 1 July 2024 P2P platform operators must submit the following three (3) types of data:
(i) Data on lending transactions (including customers’ information and lending quality);
(ii) Periodic financial reports (for example, profit/loss statements, changes in equity, cash flow statements, quality of outstanding funding, activity reports); and
(iii) Incidental reports (for example, reports on fraud, legal disputes, and operational disruptions).

The P2P lending industry in Indonesia has been increasingly regulated as it matures, in order to improve corporate governance levels by P2P platform operators and to maintain the sustainability of P2P lending businesses, amidst various challenges.

The OJK’s published Roadmap for Developing and Strengthening the P2P Industry states that the focus during the next 2 years (2025 and 2026) will be on consolidation of P2P businesses to create momentum for higher growth. During this phase, all P2P platform operators are expected to have fulfilled the minimum IDR 12.5 billion equity requirement (as of July 2025).

2. Carbon Capture and Storage (CCS) Regulation

The government of Indonesia (“**GOI**”) has issued the long-anticipated Presidential Regulation No. 14 of 2024 on Implementation of Carbon Capture and Storage (“**CCS**”) Activities (“**PR 14/2024**”), which, together with Regulation of Minister of Energy and Mineral Resources (“**MEMR**”) No. 2 of 2023 (“**MEMR Reg 2/2023**”), establishes a comprehensive regulatory framework for the implementation of CCS activities in Indonesia, in an effort to achieve net-zero emissions by 2060.

Prior to the issuance of PR 14/2014, oil and gas contractors with business licenses (“**Contractors**”) were the only parties permitted to engage in CCS activities within the designated working areas, after obtaining approval from the MEMR or SKK MIGAS/BPMA. However, PR 14/2024 permits other business entities to engage in CCS activities also, provided that: (i) the relevant entity obtains an Exploration Permit (*Izin Eksplorasi*) and/or a Storage Operation Permit (*Izin Operasi Penyimpanan*) from the MEMR, and (ii) the CCS activities are within the areas designated by the MEMR as Carbon Storage Permit Areas (*Wilayah Izin Penyimpanan Karbon*).

In addition, unlike MEMR Reg 2/2023, PR 14/2024 expressly allows cross-border CCS activities, subject to a bilateral agreement with the exporting country, fulfillment of minimum domestic carbon allocation, cross-border transportation of carbon emission requirements, and compliance with other relevant requirements.

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Malaysia Authors: Wan May Leong and Ryan Heng

1. The Enhanced Beneficial Ownership Reporting Framework

The Companies (Amendment) Act 2024 (“**Amendment**”) was gazetted on 2 February 2024 and came into effect on 1 April 2024. Among other matters, the Amendment introduces an enhanced framework for disclosure and reporting of beneficial ownership (“**Enhanced BO Reporting Framework**”). The key features of the Enhanced BO Reporting Framework include:

(i) **Definition of “beneficial owner”:** Previously, “beneficial owner” was defined in the Companies Act 2016 as the ultimate owner of the shares, and did not include a nominee of any description. The definition of “beneficial owner” has been widened by the Amendment to mean “*a natural person who ultimately owns or controls a company and includes a person who exercises ultimate effective control over a company.*” The Guidelines for the Reporting Framework for Beneficial Ownership of Companies (“**Guidelines**”) issued by the Companies Commission of Malaysia (“**CCM**”) clarified that “ultimate effective control” covers situations in which an individual holding less than 20% of the shares or voting shares of a company is deemed a beneficial owner, if that individual exercises significant influence or control over the directors or the management of the company.

(ii) **Register of beneficial owners:** Companies in Malaysia are required to keep a register of beneficial owners (“**BO Register**”) at the registered office. If there are any changes to beneficial ownership information (“**BO information**”), the company is required to lodge a notice of any changes to the information in the BO Register with the CCM within 14 days of the change. Starting 1 April 2024, companies need to give notice of BO information via the CCM’s Electronic Beneficial Ownership System (“**EBO System**”).

(iii) **Disclosure and reporting obligations:** It is mandatory for companies to issue written notices to (a) their members, and (b) any person the company knows or has reasonable grounds to believe is a beneficial owner of the company, to obtain required BO information and/or any changes thereto.

(iv) **Access to BO information:** The Guidelines provide that BO information is not publicly available. Nonetheless, in consideration that BO information could be critical for certain persons or class of persons when they are discharging responsibilities under other written laws, the Ministry of Domestic Trade and Cost of Living is empowered to establish the persons who may access the BO Register (for instance, law enforcement agencies, public authorities and reporting institutions gazetted under the Companies Act 2016).

Businesses also should take note that companies are given 3 months from 1 April 2024 to lodge their latest BO information on the EBO System. Further details on these matters will be released by CCM in due course.

2. Cyber Security Bill 2024

The Cyber Security Bill 2024 (“**Bill**”) was passed by the House of Representatives on 27 March 2024 and the Senate on 3 April 2024. If and when the Bill comes into force, it will be the first overarching cybersecurity legislation in Malaysia, which will serve to bolster national cybersecurity and to address cybersecurity threats alongside existing legal frameworks. such as the Personal Data Protection Act 2010. The notable proposed features of the Bill include:

(i) **National Critical Information Infrastructure (“NCII”):** The Bill defines NCII as “a computer or computer system, where the disruption or destruction thereof would have a detrimental impact on the delivery of any service essential to the security, defence, foreign relations, economy, public health, public safety or public order of Malaysia, or on the ability of the Federal Government or any of the State Governments to carry out its functions effectively.” The Bill also specifies NCII sectors as (a) government, (b) banking and finance, (c) transportation, (d) defence and national security, (e) information communication and digital, (f) healthcare services, (g) water sewerage and waste management, (h) energy, (i) agriculture and plantation, (j) trade, industry and economy, and (k) science, technology and innovation sectors.

(ii) **Duties of NCII Entities:** An entity that is designated as an NCII entity is subject to duties under the Bill, which include the duties to: (a) implement the measures, standards, and processes specified in the code of practice issued by the respective NCII sector leads, (b) conduct cyber security audits and risk assessments, and (c) notify the Chief Executive of the National Cyber Security Agency and NCII sector leads when there is a cyber security incident.

(iii) **Imposition of a licensing requirement for cyber security service providers:** The Bill proposes that providers of prescribed cyber security services will be subject to a new licensing framework. Nonetheless, the scope of those licensed cyber security services has yet to be prescribed by the Minister.

(iv) **Extra-territorial application:** The Bill intends to have extra-territorial effect and will apply to any person, of any nationality or citizenship, outside and within Malaysia. Foreign businesses may be subject to the Bill if they are connected/related to NCIIs that are wholly or partly in Malaysia.

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Philippines Michelle Marie F. Villarica and Steffi C. Sales

1. Issuance of the Public-Private Partnership Code Implementing Rules and Regulations

On March 22, 2024, the PPP Center published the Implementing Rules and Regulations ("**IRR**") of Republic Act No. 11966, or the "Public-Private Partnership Code of the Philippines" ("**PPP Code**"), following the PPP Code's effection on December 23, 2023. The IRR provide details concerning proper enforcement of the PPP Code and formally take effect on April 6, 2024.

The IRR (among others): (i) expands the definition of a PPP contract by specifying that it is a contractual arrangement between an implementing government agency and a private partner to finance, design, construct, operate, and maintain, or any combination or variation thereof, "Infrastructure or Development Projects and Services" which are typically provided by the public sector, where each party shares in the associated risks, and where the investment recovery of the private partner is linked to performance, (ii) further enumerates in a non-exhaustive list the kinds of projects classified as "Infrastructure or Development Projects and Services," and enumerates the public infrastructure projects that are excluded from the coverage of the PPP Code, and (iii) specifies the administrative, civil, and penal sanctions for violating PPP Code requirements, imposing, among others, a fine of PHP1 million to PHP5 million and the penalty of imprisonment of three to six years for individuals who commit any of the acts prohibited under the PPP Code.

2. Updated SEC Fines and Penalties for Late and Non-Filing of Reportorial Requirements

On March 27, 2024, the Philippine Securities and Exchange Commission ("**SEC**") published Memorandum Circular No. 6-2024 ("**MC**"), which updates the schedule of fines and penalties for the late and non-submission of reports that companies are required to file with the SEC. The MC took effect on April 1, 2024.

Previously, the SEC imposed a fine ranging from PHP500 to PHP1,000 for each delayed or unsubmitted reportorial requirement. Now, the imposable fines for late filing of a report for stock corporations are based on the corporation's retained earnings, ranging from PHP5,000-PHP25,000 plus PHP1,000 per month of delay for the first offense to PHP9,000-PHP45,000 plus PHP1,000 per month of delay for the fifth offense. For reports that were not filed, the imposable fines now range from PHP10,000-PHP30,000 plus PHP1,000 per month of delay for the first offense to PHP18,000-PHP54,000 plus PHP1,000 per month of delay for the fifth offense.

3. Clarified Guidelines for Tax Exemptions of Retirement Benefits

Republic Act 4917 grants income tax exemptions for retirement benefits granted pursuant to a tax-qualified retirement plan, as long as the retiring employee meets the following criteria: (i) been in the service of the same employer for at least ten (10) years, and (ii) is 50 years old or older.

The Philippine Bureau of Internal Revenue ("**BIR**") issued Revenue Memorandum Circular No. 13-2024 last January 22, 2024 (the "**BIR Circular**"), clarifying the treatment of transferred employees in the context of a valid merger. The BIR Circular clarifies that in the case of a transfer of employees from one "participating company"[1] to another within a "multi-employer plan"[2] due to a valid merger, the employee's aggregate years of service in both companies are considered in computing the prescribed 10-year period; provided that the employee did not receive any separation pay from the acquired company. Prior to the BIR Circular, employees transferred from one company to another could not sum up their total years of service in both companies to avail of the tax exemption benefits under Republic Act 4917.

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[1] Under the BIR Circular, "Participating Companies" refer to two or more related reporting entities contributing for the benefit of its retiring officials and employees. Reporting entities are considered related in this context if they are either parent, subsidiary, or fellow subsidiary, of any Participating Company/Companies.

[2] Under the BIR Circular, a "multi-employer plan" refers to a retirement plan to which Participating Companies referred to above contribute for the benefit of its retiring officials and employees.

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Singapore Authors: Melissa Tan and Chin Su Xian

1. Changes to Qualifying Salary of Employment Pass Holders

The Ministry of Manpower ("**MOM**") has announced on 4 March 2024 that the current fixed monthly salary criteria of S$5,000 for new Employment Pass ("**EP**") applications will be increased to S$5,600 with effect from 1 January 2025, and with effect from 1 January 2026 for EP renewals. This EP qualifying salary will continue to increase progressively with age from age 23, up to S$10,500 at age 45 and above. For the financial services sector, the EP qualifying salary will be raised from S$5,500 to S$6,200 and will continue to increase progressively with age from age 23, up to S$11,800 at age 45 and above.

In addition to meeting the qualifying salary, EP candidates must pass a points-based Complementarity Assessment Framework ("**COMPASS**") for new EP applications from 1 September 2023 and for EP renewals from 1 September 2024. COMPASS evaluates EP applications based on a holistic set of (a) individual attributes (i.e. salary, qualifications, being on the Shortage Occupation List ("**SOL**")) and (b) firm-related attributes (i.e. diversity, support for local employment, meeting specific assessment criteria on innovation, or internationalisation activities): https://www.mom.gov.sg/passes-and-permits/employment-pass/eligibility#compass.

With the implementation of COMPASS, all post-secondary diploma and above qualifications declared will have to be supported with a third-party verification proof. This requirement will apply to new EP applications from 1 September 2023, and renewals from 1 September 2024. Such verification is mandatory so long as the qualification is declared in the EP application. Employers(applying on behalf of the EP candidate) who require points from these qualifications to pass COMPASS have to declare them in their EP application.

2. Amendment to the Cybersecurity Act 2018

The Cyber Security Agency of Singapore ("**CSA**") has proposed to amend the Cybersecurity Act 2018 ("**Act**") through the Cybersecurity (Amendment) Bill ("**Bill**"), which has been first read in Parliament on 3 April 2024, after a period of public consultation between 15 December 2023 to 15 January 2024 on the Bill. The Bill seeks to ensure that Singapore's cybersecurity laws remain fit-for-purpose to address the emerging challenges in cyberspace, as well as the evolving technological operating context.

The Bill will update existing provisions relating to cybersecurity of critical information infrastructure ("**CII**"), such as those providing water, electricity and banking services, and expand CSA's oversight to cover the cybersecurity of systems of temporary cybersecurity concern ("**STCCs**"). In addition, it will introduce two new classes of regulated entities, entities of special cybersecurity interest ("**ESCI**") and foundational digital infrastructure ("**FDI**"), which will be subject to a light-touch regulatory treatment.

Some of the key proposed changes are as follows:
(i) Expanding the definition of the CII by introducing a separate category of "non-provider-owned CII", where the provider does not own and control the CII used for the continuous delivery of the essential services they are responsible for – such provider of essential services will be required, amongst other obligations, to obtain legally binding commitments from their computing vendors or the owners of the non-provider-owned CII to ensure that the provider of the essential service is able to discharge its duties under the Act.

(ii) Widening the scope of incident reporting, for example, expanding the types of incidents to be reported by CII owners to the Commissioner of Cybersecurity ("**Commissioner**") and granting the Commissioner the power to authorise the conduct of on-site inspections by the Deputy Commissioner, Assistant Commissioner and/or cybersecurity officer or authorised officer appointed by the Commissioner under the Act. CII owners will be required to report incidents on any part of the network under the provider's control, or incidents in respect of the network under the control of a supplier to the owner that is interconnected or communicates with the provider-owned CII, as opposed to the current obligation to report only incidents relating specifically to the provider-owned CII.

(iii) Enhancing the Commissioner's regulatory oversight beyond CII owners to include the three new categories, STCCs, ESCIs and FDIs.

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Thailand Authors: Jirapong Sriwat and Apinya Sarntikasem

1. Investment Promotion for Digital Industry

On 15 March 2024, the Board of Investment of Thailand (the "**BOI**") published Notification No. Sor. 2/2567 regarding Improvement on Investment Promotion for Digital Industry (the "**DI Notification**"). This DI Notification extends investment promotion to companies engaged in improving software platforms for digital services or digital content.[3] However, such companies will face stricter conditions compared to other digital service businesses eligible for BOI incentives. For instance, they will not qualify for corporate income tax exemption, be granted land ownership for business operations, and must commence operations within 12 months of receiving the investment promotion certificate, without extension. Despite these limitations, promoted companies can still avail themselves of other BOI incentives such as import duty exemptions on machinery and permission to bring foreign skilled workers and experts into Thailand to work in the promoted activity.

Additionally, the DI Notification introduces additional conditions for investment promotion in software platform development for digital services or digital content. These include the requirement to commence operations within 12 months of receiving the investment promotion certificate, without extension, and no longer being allowed to extend the period for importing machinery. On the other hand, for data center businesses, the requirement of a minimum site of 3,000 square meters for business operation is removed. Instead, a data center must have an electrical system which can handle no less than 2MW of IT Load. The data center is also not required to obtain ISO 9000 or ISO 14000 certification or to meet other equivalent standards for its business operation.

2. Measure to Promote Electronic Vehicles Usage (EV 3.5)

On 29 January 2024, the Excise Department issued the Notification regarding the Rules, Methods and Conditions for Privileges under Phase Two of the Electronic Vehicles Usage Promotion Measure for Cars and Motorcycles (the "**EV Notification**"), which came into effect on 1 January 2024. This EV Notification was published as part of the Thai government's second phase policy to promote the adoption of electronic vehicles ("**EVs**"). Under the EV Notification, eligible persons, such as industrial operators and importers who are appointed as official distributors may apply for privileges under phase two of the EV promotion measure. These privileges include import duty exemption or reduction, as well as monetary subsidies, depending on the type of vehicles manufactured or imported. Additionally, the EV Notification mandates that manufacturers who receive privileges under the EV promotion measure must gradually increase the use of components made in Thailand starting from 1 January 2026 onwards. Furthermore, they are required to manufacture EVs as compensation for importation at a rate of two manufactured vehicles for every one imported vehicle.

3. Data Protection for Criminal Records

The Notification of the Personal Data Protection Committee regarding Rules on Protection Measures for the Collection of Personal Data related to Criminal Records not Conducted under the Control of Authorized Agency under the Law B.E. 2566 (2023) (the "**CR Notification**") was published in the Government Gazette on 8 January 2024 and will come into force 90 days after its publication, on 7 April 2024. Under the CR Notification, data controllers are only permitted to collect personal data related to criminal records, which include data on criminal investigations, proceedings, or sanctions, if it is official information or certified by a government agency, and only when permitted by law or with explicit consent from the data subject. However, the collection of criminal records with the consent of the data subject is restricted to specific purposes, such as employment. Additionally, the data controller is required to ensure the implementation of necessary organizational and technical measures, which may include physical measures, for the collection of such collection.

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[3] Before this Digital Industry Notification was published, the only companies eligible to obtain investment promotion from the BOI in relation to the digital industry were those operating a business of software platform development for digital services or digital content, data center, cloud service, international high-speed marine communication circuits service, innovation park, maker space or fabrication laboratory, co-working space, smart city area development, or smart city system development.

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Vietnam Authors: Vu Le Bang and Nguyen Thi Thanh Huong

1. Law No. 32/2024/QH15 on Credit Institutions ("New LoCI")

The New LoCI was officially adopted on 18 January 2024, and it will take effect on 01 July 2024 (except for the provisions relating to the enforcement of secured assets being real estate projects via the project transfer scheme, which shall be effective as of 01 January 2025). The New LoCI brings forth several material amendments and supplements in comparison to the Law No. 47/2010/QH12 on Credit Institutions ("**Current LoCI**"), as follows:

(i) *Decrease in credit limit*: As of 01 July 2024, the credit limit at commercial banks or foreign bank branches will be decreased gradually, with a specific roadmap, from 15% to 10% of the bank's equity for a customer, and from 25% to 15% of the bank's equity for a customer and its related persons. For non-bank credit institutions, as of 01 July 2024, the credit limit applied to a customer will be decreased from 25% to 15% of such credit institution's equity, while that applied to a customer and its related persons will be decreased from 50% to 25%.

(ii) *Consolidated licensing procedures*: The establishment license granted by the State Bank of Vietnam under the New LoCI for credit institutions, foreign bank branches, representative offices of foreign credit institutions, and other foreign organizations with banking activities will be recognized as their business registration certificates. As such, the credit institutions are no longer subject to business registration procedures under the enterprises law as per the Current LoCI.

(iii) *Decrease of share ownership limit*: Under the New LoCI, in a credit institution that is a joint stock company, the ownership limit imposed on an institutional shareholder will be decreased from 15% to 10% of the charter capital of such credit institution, and the ownership limit imposed on a shareholder (either an individual or institutional) and its related persons will be decreased from 20% to 15% of the charter capital of such credit institution.

(iv) *Broader the definition of related person*: The New LoCI supplements certain groups of related persons, including (a) the subsidiary of the subsidiary of a credit institution, and (b) paternal grandparents, maternal grandparents, paternal grandchildren, maternal grandchildren, brothers and sisters of a mother or father, and nephews and nieces of an individual.

(v) *Permit the transfer of mortgaged assets being real estate projects*: The New LoCI expressly allows the credit institutions, branches of foreign banks, debt management and asset exploitation companies of credit institutions, and asset management companies of Vietnamese credit institutions to transfer all or part of real estate projects being collateral to recover debts without being subject to regulations on conditions of real estate business entities under the Law on Real Estate Business.

2. Law No. 31/2024/QH15 on Land ("New Land Law")

The New Land Law was adopted on 18 January 2024 and will take effect on 01 January 2025. Below are several significant changes introduced by the New Land Law:

(i) *Change in the concept of foreign-invested enterprises ("**FIEs**")*: Currently, all FIEs, regardless of their foreign capital ownership ratio, are subject to the same strict regulations regarding land use right ("**LUR**"). However, under the New Land Law, a FIE refers to a company of which more than 50% of the total shares are held by foreign investors, either directly or via their subsidiaries, as regulated by Article 23 of the Law on Investment. As such, unlike the current land law, the remaining entities including FIEs with 50% or less foreign ownership ratio as well as their subsidiaries or affiliates will now enjoy the same treatment as domestic entities under the New Land Law.

(ii) *Extension of the rights of FIEs*: In comparison with the current regulations, the rights of the FIEs under the New Land Law are extended. For instance, (a) a FIE that leases land with annual rent payments is entitled to sell or lease the lease right in the land lease contract, and (b) a FIE is entitled to receive transfer of LUR in industrial parks, industrial clusters, and high-tech zones.

(iii) *Abolition of land price bracket*: Under the New Land Law, the land price bracket issued by the Government, which defines the maximum and minimum price of each type of land for the determination of financial obligations of land users, is abolished, and the annual land price table and the specific land price will be calculated based on, among others, market principles.

(iv) *Clarification of cases of land allocation and land lease*: The New Land Law provides clearer regulations on methods to acquire LUR in the form of either land allocation or land lease, which are auctions of LUR, and the selection of investors of projects using land by bidding and agreeing on acquisition of LUR. Specifically, the New Land Law describes the cases where each of these methods are applied, conditions on land to apply the eligible method, and conditions on organizations or individuals participating in each method of land acquisition.

(v) *Extension of permitted cases of mortgage of LUR*: The New Land Law newly permits domestic economic organizations leasing land from the State to mortgage LUR and assets attached to land (in the case of land allocation or land lease under a lump sum rent payment) or to mortgage assets attached to land (in the case of land lease under annual rent payments) at other domestic economic organizations and individuals, while under current land laws, they may mortgage LUR and/or assets attached to land (as the case may be) with credit institutions operating in Vietnam only. Such change is expected to increase the financial resources of economic organizations using land.

Ⓒ Nishimura & Asahi 2024

India Authors: Taeko Suzuki and Isha Shah

1. Conditions for exemptions under the Factories Act in Haryana to allow women to work night shifts

On 14 March 2024, the Haryana Government, pursuant to Section 66 of the Factories Act, 1948 ("**Factories Act**"), notified conditions which will apply to factories availing exemptions under the Factories Act for employing women during a night shift (i.e., from 7:00 PM to 6:00 AM) in respect of their safety and security.

The conditions include, *inter alia*: (a) compliance with the provisions of the Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act, 2013 ("**POSH Act**") and constituting a separate internal complaints committee ("**ICC**") at every office or administrative unit workplace, (b) displaying the order regarding ICCs and policy under the POSH Act in conspicuous places at the workplace, (c) employing women workers in a batch of not less than 10, (d) providing transportation to women workers from their residence and back, along with security guards (including a woman security guard), trained and pre-screened drivers, GPS trackers, and proper communication channels in each vehicle, (e) deputing woman supervisors, shift-in-charge and security guards during night shifts, (f) obtaining the consent of women workers working during the night shift, and (g) allowing women workers from all shifts to express grievances (through their representatives) in a monthly meeting with their occupier.

Similar conditions for exemptions have been notified by the Government of Uttar Pradesh *vide* notification dated February 19, 2024 and by the Government of Rajasthan under the Rajasthan Shops and Commercial Establishments Act, 1959 *vide* notification dated March 7, 2024.

2. FDI in the Space Sector

On 4 March 2024, the Indian Government issued Press Note 1 of 2024 liberalizing foreign direct investment ("**FDI**") in the space sector by permitting investments under the automatic route. The Press Note was given effect on April 16, 2024, through the Foreign Exchange Management (Non-debt Instruments) (Third Amendment) Rules, 2024.The specified investment thresholds are as follows:

Specified activity	FDI cap and entry route
Manufacturing of components and systems or sub-systems for satellites, ground segments and user segments	Automatic route: 100%
Satellites-manufacturing and operation, satellite data products, ground segments and user segments	Automatic route: up to 74% Government route: beyond 74%
Launch vehicles and associated systems or subsystems, creation of spaceports for launching and receiving spacecraft	Automatic route: up to 49% Government route: beyond 49%

3. Waiver of stamp duty for IT and ITES projects in Maharashtra

On 1 February 2024, the Government of Maharashtra, pursuant to Section 9 of the Maharashtra Stamp Act, 1958 and in accordance with the New Information Technology and Information Technology Enabled Services Policy of Maharashtra State, 2023 ("**IT Policy 2023**"), notified certain exemptions on full and partial waiver of stamp duties on new and existing projects related to IT and ITES. Subject to certain conditions, eligible IT and ITES projects have been granted full or partial waiver of stamp duties for certain instruments, *inter alia*, conveyance, lease, deposit of title deeds, merger, de-merger and reconstruction, mortgage, security bonds, hypothecation, pawn or pledge. The exemption is valid from 27 June 2023 to 26 June 2028 or till the new policy is announced.

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Myanmar Author: Saw Nyan Htun

1. Qualifications for Insolvency Practitioners

On 31 January 2024, the Supreme Court of the Union issued qualifications for Insolvency Practitioners under the Insolvency Law, via Notification No. 130/2024. Insolvency Practitioners are persons registered under the Insolvency Law to act as receivers, rehabilitation managers, rehabilitation advisors, supervisors of a rehabilitation plan, liquidators, and/or trustees, who may be appointed to fill these roles pursuant to the Insolvency Law. Insolvency Practitioners must be either a fully certified public accountants or advocates with at least with 10 years of professional experience. However, no announcements regarding registration of Insolvency Practitioners have been made.

2. Directive on Agent Banking Services

On 6 February 2024, the Central Bank of Myanmar ("**CBM**") issued a directive on agent banking services ("**Directive**") to provide financial services to people who previously had no access to banking services. The Directive came into force immediately.

The Directive establishes the roles of: (i) banks, (ii) agents (which are the entities the CBM allows to engage in agent banking services on behalf of the bank, by executing an agreement with the relevant bank), and (iii) the CBM, in connection with the implementation of agent banking services that are permitted under this Directive, as provided in the last paragraph of this article.

The Directive also sets forth the application process for banks appointing an agent for banking services, including required information and evaluation criteria for the agent. Banks are responsible for their appointed agents in terms of actions, risk management, training, internal control systems, and other relevant matters. The CBM is responsible for scrutinizing and granting or rejecting applications for the provision of agent banking services, including monitoring, regulating banking activities, and conducting field inspections.

Under the Directive, the agent may engage in the following banking services, as agent banking services, by executing an agreement with the bank:

(i) cash deposits and withdrawals;
(ii) collecting invoices and making payments to the bank;
(iii) collecting loans and collecting documentary evidence relating to loan applications;
(iv) domestic remittances;
(v) pension withdrawals and disbursements of social benefits such as allowances provided by the Union or society;
(vi) balance inquiries; and
(vii) document correspondence services between banks and customers.

3. Fees for Registration of Industrial Design and Copyrights

The Ministry of Commerce ("**MOC**") issued a fee schedule for registration of industrial designs, as Notification No. 2/2023 dated December 29, 2023. The MOC also issued a schedule of fees for registration of copyrights, as Notification No. 1/2024 dated February 13, 2024. Both Notifications include information about various types of registration service fees. For example, according to the Notification No.2/2023, the fee for examining an application for registration of industrial design rights is MMK120,000.

Ⓒ Nishimura & Asahi 2024

Taiwan Author: Cheng-Yi Chiang

1. Electronics Signature Act to Receive a Major Revamp

On 29 February 2024, Executive Yuan, the executive body of Taiwan proposed an amendment to the Electronics Signature Act (the **"ESA"**), which has not been amended since its 2001 enactment. The ESA amendment bill (the **"Bill"**) has advanced to the legislature and is set to be passed in 2024. A few of the major changes to be made to the ESA are as follows:

(i) Clarifications on the Legal Effect of Electronic Records and Electronic Signatures

The ESA lacks provisions explicitly defining the legal effect of electronic records and signatures. Despite the fact that courts rarely deny the legal effect of documents or signatures merely due to their digital form, the absence of clear doctrine has led to hesitance in their adoption. The Bill stipulates that the legal effect of electronic records and electronic signatures are not to be denied merely due to their digital form.

(ii) Easing of the Preconditions of the Employment of Electronic Records and Electronic Signatures

Under the ESA, explicit counterparty consent is necessary to employ electronic records or electronic signatures. However, the Bill stipulates that the counterparty only be given a reasonable opportunity to opt out from their employment, and be notified that consent to their employment would be presumed if it does not opt out. Namely, according to the Bill, counterparty consent to the employment of electronic records or electronic signatures will be presumed if it does not opt out despite being notified with the opportunity to do so.

(iii) Expansion to the Application of Electronic Signatures

According to the ESA, a governmental agency may, at its own discretion, prescribe to rule out the usage of electronic records or electronic signatures under its authority. In the Bill, however, it is stipulated that usage of electronic records or electronic signatures only may be ruled out if the law provides so or otherwise authorises the governmental agency to do so. However, the updated ESA will not be applicable in court procedures, and therefore the employment of electronic records or signatures in court procedures will be subject to relevant procedure codes.

2. Amendments to TWSE Rules on the Preparation and Filing of Sustainability Reports

The Taiwan Stock Exchange (**"TWSE"**) rules on preparation and filing of sustainability reports (the **"Rules"**) was amended and entered into force on 26 January 2024. The Rules stipulate which, when, and how companies listed on TWSE are obliged to publish a sustainability report each year. The amendment to the Rules expands the scope of companies subject to the obligation of publishing sustainability reports.

According to the pre-amendment Rules, (1) companies in food industries, chemical industries and the financial or insurance sector, (2) companies in which food and beverage revenue account for 50% or more of its total revenue, and (3) companies with paid-in capital of more than 2 billion New Taiwan Dollars have been obliged to publish sustainability reports. After the amendment, starting from 2025, every company listed on TWSE, regardless of its nature, becomes obliged to publish sustainability reports every year, whereas (1) companies in food industries, chemical industries and the financial or insurance sector, and (2) companies in which food and beverage revenue account for 50% or more of its total revenue are required to publish sustainability reports with enhanced disclosure on specific sustainability indicators in accordance with their respective industries.

According to the amended Rules, companies listed on the TWSE are required to reference Universal Standards and Sector Standards published by the Global Reporting Initiative (GRI) and publish their sustainability reports by the end of 31 August of every year. Documentations published by the Sustainability Accounting Standards Board (SASB) may also be referenced.

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Hong Kong Author: Ryuichi Sakamoto

1. Regulation of Stablecoin Issuers

A public consultation paper titled "Legislative Proposal to Implement the Regulatory Regime for Stablecoin Issuers in Hong Kong" ("**Paper**") was issued on 27 December 2023 by the Financial Services and the Treasury Bureau and the Hong Kong Monetary Authority ("**HKMA**"). The Paper seeks feedback on a legislative proposal ("**Proposal**") to regulate issuers of stablecoins, in particular those purporting to maintain a stable value with reference to one or more fiat currencies (i.e. fiat-referenced stablecoin, "**FRS**"). The key point is that no entity shall issue FRS in Hong Kong or actively market FRS issuance to the Hong Kong public unless it holds an FRS issuer license. The following are some of the major requirements proposed by the Paper for obtaining the license:

(i) An FRS issuer must ensure that the value of the reserve assets backing an FRS is at least equal to the par value of the FRS in circulation at all times.
(ii) FRS users should have the right to redeem their FRS at par value with the FRS issuer and have a claim on the reserve assets.
(iii) An FRS issuer must have adequate financial resources for operating its FRS issuance business, including a minimum paid-up share capital. It is proposed that the minimum paid-up share capital will be either HKD25,000,000 or two percent of the par value of FRS in circulation, whichever is higher.
(iv) An FRS issuer must publish a white paper to disclose general information about itself, the rights and obligations of the FRS users, the FRS stabilisation mechanism, reserves management arrangements, the underlying technology and the risks.
(v) Controllers, chief executives and directors of an FRS issuer must be fit and proper persons, and their appointment, together with any changes in ownership or management of the FRS issuer, would require the prior consent of the regulator.
(vi) An FRS issuer must have in place appropriate risk management processes and measures for its operations.

2. Amendment to the Cross-boundary Wealth Management Connect Pilot Scheme

The People's Bank of China, HKMA, and the Securities and Futures Commission ("**SFC**") issued their respective amended rules for the Cross-boundary Wealth Management Connect Pilot Scheme ("**WMC**") in the Guangdong-Hong Kong-Macau Greater Bay Area ("**GBA**") on 24 January 2024. The WMC, consisting of the northbound scheme and southbound scheme, was initially launched in September 2021 and permits eligible residents in the GBA to invest in cross-boundary eligible wealth management products. Since its launch, the WMC has contributed to the enhanced connectivity between Mainland China and Hong Kong in relation to the distribution of the wealth management products across the GBA. This amendment aims to further enhancement of the WMC and the following are some of the major amended points for the financial services industry in Hong Kong:

(i) **Participation by SFC-licensed corporations**
The amended rules allow not only banks but also SFC-licensed corporations ("**LC**"), to participate in the WMC, subject to applicable rules issued by the SFC. (e.g., LC should partner with an eligible Mainland broker and work closely with it, put in place adequate systems, internal control measures and operating procedures in accordance with the requirements set out in the SFC's guidance, etc.)

(ii) **Eligible investment products**
Under the old rules, eligible investment funds for the southbound scheme were limited to Hong Kong domiciled funds authorised by the SFC and assessed as "non-complex" and "low risk to medium risk". The amended rule expanded the eligible investment funds to funds domiciled in Hong Kong and authorised by the SFC (1) which primarily invest in Greater China equities and are assessed as "non-complex", or (2) which are assessed as "low" risk to "medium to high" risk and "non-complex", but excluding high-yield bond funds and single emerging market equity funds.

(iii) **Individual investor quota**
Individuals who participate in the WMC are subject to an individual investment quota. The individual investor quota for each investor under the southbound scheme was increased from RMB 1 million to RMB 3 million.

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United Arab Emirates Authors: Masao Morishita and Yurika Murabayashi

1. New Federal Law on Financial Restructuring and Bankruptcy

Federal Law No. 51 of 2023 on Financial Restructuring and Bankruptcy (the "**New Law**") will come into effect on May 1, 2024. This law abrogates and replaces Federal Law No. 9 of 2016 on Bankruptcy (the "**Old Law**"). While regulations and decisions implementing the Old Law will remain in effect until they are replaced by the New Law, the New Law will introduce significant changes that will impact bankruptcy proceedings in the UAE. The New Law amends a number of points, including the following:

(i) **Introduction of the bankruptcy unit:** The New Law will introduce a specialized division within the courts, which is overseen by a senior Court of Appeal judge, dedicated to managing and overseeing bankruptcy and restructuring cases to support the Bankruptcy Court.

(ii) **Preventive Settlement:** The Preventive Composition will be changed to a more user-friendly mechanism called "Preventive Settlement." The procedure (Preventive Settlement) can now be completed quickly and flexibly, as the appointment of a trustee, which was required under the Preventive Composition under the Old Law, is no longer necessary. The Preventive Settlement is also more convenient than the Preventive Composition under the Old Law since it does not interfere with the normal business of the debtor.

(iii) **Moratorium:** The debtor is to be suspended from court proceedings and execution proceedings pending against it for three to six months from the date of the decision to initiate the proceedings of the Preventive Settlement, amending the rule under the Old Law, which was set at a maximum of ten months. Similarly, court proceedings and enforcement proceedings against the debtor are stayed as soon as the commencement of bankruptcy proceedings is decided, but this stay remains in force until ratification of the rehabilitation plan or termination of the bankruptcy proceedings, with no time limit.

(iv) **Debtor's obligation to initiate proceedings:** Unlike the Old Law, which obliged the debtor to initiate bankruptcy proceedings in the event of a cessation of payments for 30 days or more, under the New Law the debtor is not obliged to initiate bankruptcy proceedings.

(v) **Modification of key definitions**: The New Law modifies and clarifies key definitions under the Old Law, including "related party," "the debtor's assets," "bankruptcy register," and others. Notably, the definition of "the debtor's assets" will be expanded to encompass all movable and immovable property owned by the debtor worldwide.

(vi) **Scope:** Similar to the Old Law, the New Law is not applicable to the ADGM and the DIFC, as these areas have their own bankruptcy laws in place.

2. New Federal Law on Public-Private Partnerships

Federal Decree-Law No. 12 of 2023 (the "**PPP Law**") on public-private partnerships, which sets forth the general framework for partnerships between federal government entities and the private sector, entered into force on December 1, 2023. The PPP Law applies to partnership projects that are proposed by a federal entity and wholly or partially funded by the private sector with some exceptions.

The PPP Law sets out the procedures and other rules for public-private partnerships organized by federal entities, including provisions on government guarantees and incentives that may be granted to private sector partners; however, further details will have to await the contents of the Cabinet Decision and Guidebook (Partnership Projects Guidebook) that will be enacted in relation to the PPP Law. The PPP Law applies to projects organized by federal entities and does not apply to projects organized by individual emirates, such as the Emirate of Dubai and the Emirate of Abu Dhabi.

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Japan Authors: Hiroki Kaga and Aya Okada

Announcement by Tokyo Stock Exchange regarding "Revision of the Listing Rules in Order to Expand English Disclosure in the Prime Market"

On February 26 2024, Tokyo Stock Exchange ("**TSE**") announced the "Revision of the Listing Rules in Order to Expand English Disclosure in the Prime Market" ("**Amended Rules**".)

(i) Background of the Amended Rules

During recent years, English disclosures in Japan have been progressing due to the development of regulations to facilitate such efforts including the revision of the Corporate Governance Code in June 2021 to recommend English disclosures (Supplementary Principles 3.1.2), and the market reclassification of the listed companies in April 2022positioning the Prime Market as "a market for companies that focus on constructive dialogue with global investors." Especially, English disclosure efforts have progressed in companies listed on the Prime Market. According to the "Summary Report of the English Disclosure Implementation Status Survey" published by the Listing Department of TSE in March 2022 and January 2024, the proportion of companies disclosing in English in companies in the Prime Market as of end of 2020 was 79.7%, while such rate increased to 98.2% as of the end of 2023. On the other hand, according to the "Results of the Survey of Overseas Investors on English Disclosure by Japanese Companies" published by the Listing Department of TSE in August 2023, the results show that overseas investors are still not satisfied with the current status of English disclosure by Japanese listed companies, although they admitted that progress had been made. Many of the respondents dissatisfied with the current status pointed out about the lack information in English disclosure compared to the information in Japanese disclosure, and the delay in the timing of disclosure of English-language materials. Moreover, the survey indicated that inadequate English disclosure impacted the dialogues, investment decisions and exercising voting rights of the overseas investors.

In light of this situation, TSE announced the Amended Rules towards expanding English disclosure to attract more overseas investment in listed companies in Japan and encourage improvements in their corporate value through dialogue with overseas investors.

(ii) Summary of the Amended Rules

The Amended Rules suggests the following rules, and these rules are expected to be effective for disclosures made on or after April 1 2025 (However, TSE will give a grace period to listed companies that submit a document with a specific estimated date of implementation. The grace period is expected to be one year from when the rules take effect.)

a. Obligation to make efforts for English disclosure (to be stipulated in the "Matters Desired to be Observed" in the Code of Corporate Conduct)

- Prime Market listed companies should endeavour to simultaneously disclose the same material corporate information in Japanese and English. The term material corporate information shall not only mean the information necessary for the real time investment decision, but shall also include all material information necessary for the mid-term long-term analysis or exercise of voting rights.

b. Mandatory English disclosure of financial results and timely disclosure information (to be stipulated in the "Matters to be Observed" in the Code of Corporate Conduct)

- Prime Market listed companies will simultaneously disclose their financial results (annual and quarterly earnings reports, as well as any supplementary explanatory materials that are prepared and provided to investors) and timely disclosure information (corporate information disclosed in a timely manner by a listed company via TDnet, including voluntary disclosures) in Japanese and English.
- English disclosure must be made simultaneously with Japanese disclosure. However, this shall not apply in situations where simultaneous disclosure in English would cause a delay in disclosure in Japanese because urgent action is required due to the occurrence of an incident, or because the content of disclosure in Japanese is not finalized until immediately prior to disclosure due to the coordination with relevant parties.
- Not the whole text of the Japanese disclosure but part of the text or the summary of will be sufficient and the English disclosure is regarded as reference translations of Japanese disclosure. The accuracy of the translation is not subject to enforcement measures (e.g. publishing measures), however, enforcement measures may apply in cases where no English disclosure is made.

It is expected that changes to the system based on the Amended Rules will lead to further progress in English disclosure in the prime market and attract overseas investment.

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Bangladesh Authors[4]: Taeko Suzuki and Varsha Bhattacharya

1. New Offshore Banking Act, 2024

The Bangladesh Parliament passed the Offshore Banking Act, 2024 with effect from 14 March 2024.[5]

Key prescriptions under the new Act are:

(a) Foreign entities investing in Bangladesh can now open offshore banking accounts with scheduled and licensed banks in Bangladesh.
(b) Funds stored in these accounts can be freely remitted out of Bangladesh without any prior governmental permission, which was required earlier.
(c) The balance and interest in such accounts will be exempt from any tax, duty, fees or charges.
(d) Transactions in these accounts can be undertaken in five foreign currencies, including the Japanese Yen and the United States Dollar.

2. Tax exemption on export income

On 4 March 2024, Bangladesh's National Board of Revenue, in exercise of its power under Section 76(1) of the Income Tax Act, 2023, issued a Statutory Regulatory Order ("**SRO**")[6] to grant exemptions and reduced rates of tax on export income, subject to certain conditions.

According to the SRO, companies will benefit from a reduced rate of tax of 12% on their export income. Companies exporting manufactured goods produced in Leadership in Energy and Environmental Design (LEED) certified factories, most of which operate in the garments sector, will benefit from a further reduced rate of 10% on export income.

3. Establishment of Agency to Innovate (A2i)

The Government of Bangladesh issued a notification on 6 February 2024 to establish the Agency to Innovate under Section 3(1) of the Agency to Innovate (A2i) Act, 2023.[7]

The agency is autonomous, and chaired by the Information and Communication Technology Minister. The mandate of the agency is to formulate policy to encourage innovation in the information technology sector, and increase public awareness.

[4] We hereby thank Ms. Shimu Kamrunnaher from Rahman's Chambers, a Bangladesh law firm, for her support in preparation of this article.

[5] https://www.dpp.gov.bd/upload_file/gazettes/52745_38805.pdf

[6] SRO No. 44-Law/Income Tax-25/2024 dated 4 March 2024 https://nbr.gov.bd/uploads/sros/SRO_No-44_of_2024.pdf

[7] SRO No. 20-Law/2024 dated 6 February 2024 https://www.dpp.gov.bd/upload_file/gazettes/52272_37570.pdf

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Sri Lanka Authors:[8] Akihiro Kawashima

1. Enforcement of Online Safety Act to Regulate Online Content

February 1, 2024, saw the certification of Sri Lanka's Online Safety Act 2024 (the "**Act**"), which aims to, among other things, protect persons from any harm caused by false online statements. The Act mainly prohibits certain online actions by any person, in or outside Sri Lanka, that involve communication of false statements (those that: pose threats to national security, public health or order; amount to contempt of court; incite riots; or disturb religious activities) fraud, harassment, and child abuse.

The Act also specifies the establishment of an Online Safety Commission (the "**Commission**") consisting of five members. The Commission has the power to investigate actions that potentially violate the Act, and in cases where a violation is found, powers to issue notices to persons or internet service providers to stop the communication of a prohibited statement, disable access to an online location which contains a prohibited statement, or remove a prohibited statement, etc., depending on the type of such violative action. In case the persons or internet service providers, etc., do not comply with the notices from the Commission, they are found to be in violation of the Act and subject to punishment.

Penalties are provided for violation of the Act. For example, any person who poses a threat to national security by communicating a false statement will be liable for imprisonment of a term not exceeding five years or for a fine not exceeding five hundred thousand rupees, or to both such imprisonment and fine.

2. Ratification of the United Nations Convention on International Settlement Agreements Resulting from Mediation

On February 28, 2024, Sri Lanka ratified the United Nations Convention on International Settlement Agreements Resulting from Mediation (the "**Convention**"), and became the fourteenth State Party to the Convention. The Convention aims to facilitate international trade, and promotes mediation as an alternative method of resolving international commercial disputes, by providing an effective mechanism to enforce international settlement agreements by mediation.

The Convention will come into force for Sri Lanka with effect from August 28, 2024. In preparation for this, Recognition and Enforcement of International Settlement Agreements Resulting from Mediation, Act No. 5 of 2024, a domestic law, was enacted in Sri Lanka on January 31, 2024.

[8] We hereby thank Ms. Hansi Abayaratne from D.L. & F. De Saram, a Sri Lankan law firm, for her support in preparation of this article.

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Pakistan Authors[9]: Taeko Suzuki and Tomoko Nakashima

1. Trade Marks (Amendment) Act, 2023

On August 11, 2023, the Trade Marks (Amendment) Act, 2023 ("**TM Amendment Act**") received the President's approval, thereby amending the Trade Marks Ordinance, 2001.

The key provisions introduced by the TM Amendment Act are as follows:

(i) A new "*International Registration of Trademarks*" chapter dealing with international applications under the Madrid Protocol has been introduced. The provisions introduced by this chapter mainly relate to the (a) power of the Trade Marks Registry to handle international applications, (b) procedures to be followed by the Trade Marks Registry in the case where international applications originate from Pakistan, and (c) duration and renewal of international registrations.

(ii) The administrative powers of the Intellectual Property Organization of Pakistan ("**IP Authority**") have been expanded by authorising the IP Authority to appoint a trademark registrar ("**Registrar**") and other officers (i.e., those required for appropriate functioning of the Registrar). Previously, these powers were vested in the Government of Pakistan.

(iii) The proceedings handled by the Intellectual Property Tribunal has been broadened. Per the Trade Marks Ordinance, 2001, certain proceedings thereunder were handled by the District Court; however, the authority to handle those proceedings has been curtailed by the TM Amendment Act, and the Intellectual Property Tribunal is also empowered to handle them.

2. Enactment of Computer Emergency Response Team Rules, 2023

On October 3, 2023, the Federal Government of Pakistan implemented the Computer Emergency Response Team Rules, 2023 ("**CERT Rules**"). The CERT Rules aim to enhance Pakistan's defences against cyberattacks and ensure (through computer emergency response teams ("**CERTs**")) the development of related national cybersecurity platforms of Pakistan. The CERT Rules were disclosed to the public under Section 49 of the Prevention of Electronic Crime Act, 2016, with the aim of strengthening cybersecurity measures and addressing emerging cybersecurity risks and vulnerabilities at the national, sectoral, and organizational levels.

The CERT Rules established both CERTs at the national, sectoral, and organizational levels and a supervisory authority (i.e., the CERT Council established through a notification by the Ministry of Information Technology and Telecommunication), which will serve as a consultative and advisory forum for all CERTs in order to ensure the effective performance of their roles and functions through assessments and conflict resolution procedures.

The CERT Rules identify and define the scope of services for each CERT established under the CERT Rules. For example, the primary duty of the national CERT is to serve as a liaison between various CERTs at the sectoral and organizational levels, thereby facilitating prompt responses to threats to or attacks on critical data infrastructure or information systems across Pakistan.

According to the CERT Rules, the functions of CERTs are as follows:

(i) proactive functions, such as advance threat analysis, issuance of alerts, and vulnerability management;

(ii) responsive functions, such as incident reporting, response, and recovery, and incident investigation and analysis; and

(iii) sustenance functions, such as continual optimisation and technology development and implementation.

[9] We hereby thank Mr. Syed Ali Bin Maaz from Kabraji & Talibuddin, a Pakistan law firm, for his support in preparation of this article.

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Turkey Authors[10]: Taro Hirosawa

1. Amendments to Turkish Data Protection Law

On 2 March 2024, the Grand National Assembly of Turkey adopted the Justice Reform Law, which amends the Turkish Data Protection Law No. 6698. The new provisions were published in the Official Gazette on 12 March 2024, and will enter into force as of 1 June 2024.The amendments aim to harmonize data protection regulations with those of the EU, especially the European Union General Data Protection Regulation ("**GDPR**"). The amendments relate to cross-border data transfers and the processing of sensitive data. Further guidance may likely be needed in respect of implementation of the amendments, which may be provided through secondary legislation and decisions of the Turkish Data Protection Authority.

2. Recent Developments in Healthcare Legislation

(i) Medicinal Products For Human Use: From November 2023 to February 2024, Draft Guideline on the Definition of Investigational Products and the Use of Ancillary Medicinal Products for Human Use, Amendment to the Regulation on the Licensing of Medicinal Products for Human Use, Amendment to the Regulation on Variations in Licensed Medicinal Products for Human Use, Guideline on the Export Conditions Except for Pharmaceutical Warehouses, Draft Guideline on Digitalisation in Clinical Trials, and Amendment to the Guideline on Applications for Human Medicinal Products Facilities were published. Guideline on Chemical and Pharmaceutical Quality Requirements for Medicinal Products Used in Clinical Trials and Guideline on the Quality Requirements for Biological Medicinal Products Used in Clinical Trials entered into force in line with EU legislation. Also, Guideline on the Principles and Procedures of Pharmacovigilance Studies Held by Contracted Pharmacovigilance Service Providers and Marketing Authorisation Holders, Guideline on Good Clinical Practices, Guideline on Procurement of Medicinal Products from Abroad, and Guideline on the Procedures for Scheduling of Licensing Applications of Medicinal Products for Human Use were amended.

(ii) Medical Devices: Amendment to the Guideline on the Scientific Meetings and Educational Activities to be Held Within the Scope of the Regulation on the Sale, Advertisement and Promotion of Medical Devices was published on 3 January 2024, Amendment to the Guideline on the Implementation of the Regulation on the Sale, Advertising and Promotion of Medical Devices was published on 9 January 2024, and Amendment to the Guideline on Testing, Inspection and Calibration Activities to be Conducted under the Regulation on Testing, Inspection and Calibration of Medical Devices was published on 20 February 2024.

(iii) Cosmetics: The Information Guideline on Cosmetic Product Responsible Persons and End Users was published on 7 December 2023, and the Guideline Consolidating the Guideline on Cosmetic Product Information File, Responsible Technical Personnel, Product Safety Assessors and Trainings came into force on 12 December 2023.

(iv) Healthcare Services: The Regulation on Private Healthcare Facilities Engaged in Outpatient Diagnosis and Treatment was published on 16 January 2024, the Amendment to the Regulation on Private Hospitals was published on 16 January 2024, and the Law No. 7496 on Amendments to Certain Health Related Laws and Decree Law No. 663 was published on 1 March 2024.

3. Recent Developments under Turkish Competition Law

2023 was a significantly active year for the Turkish Competition Authority (the "**TCA**"). The TCA conducted in-depth assessments into digital markets, leading to amendments to e-commerce law. There is now a more stringent regulatory environment for online marketplaces and for other participants in the e-commerce sector.

The TCA completed 2023 by advancing commitment and settlement procedures. The final quarter of 2023 saw significant revisions to the Regulation on Active Corporation for Detecting Cartels. The key amendments relate to cartel facilitators and the leniency mechanism, extending support for leniency applications concerning violators not subsequently identified as cartels and adjusting discount ranges for administrative fines.

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[10] This newsletter is prepared based on the publications of Paksoy, a major Turkish law firm, dated 29/02/2024 (*Turkish Competition Law Newsletter – 2024 Winter Issue*), 13/03/2024 (*Recent Developments in Healthcare Legislation)*, and 14/03/2024 (*Amendments to Turkish Data Protection Law soon to enter into force*).

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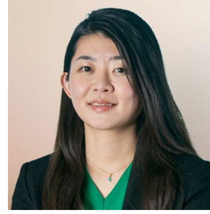

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