

# Technology Market Scan

## ASIA-PACIFIC

### BANGLADESH

#### Government moves to ease collateral requirements

The government is set to introduce an innovative financing model under a new law to enable small businesses and startups to show their moveable assets as collateral with a view to nurturing entrepreneurs and helping them secure loans. A draft law for the collateral protection for movable assets has already been formulated, according to a finance ministry official. The ministry will submit it to the cabinet by June 30 next year for approval.

The law is expected to provide local technology startups a shot in the arm as they always find it difficult to borrow from local banks and non-bank financial institutions due to a dearth of collaterals considering the nature of their business.

The proposed law is in keeping with the conditions set by the global development partners when they extended budgetary support to the government to help the country recover from the shocks triggered by the coronavirus pandemic. The government is framing the law as it wants to facilitate loans for at least 1,000 cottage, micro, small and medium enterprises (CMSMEs) and startup units by 2024. It will also put in place a more conducive regulatory environment and introduce innovative financing modalities to overcome CMSMEs' collateral issue and enhance financial intermediation. The government will help adopt an alternative credit scoring model by using digital transaction data, mainstreaming cluster and value chain financing, and promoting bank lending based on non-traditional collateral such as trade receivables and warehouse receipts.

Under the proposed law, raw materials, gold and other precious metals, patents, copyrights, work orders, furniture, tree, vehicles, agriculture and processed foods and fishery will be considered as collateral. Policies for cluster and value chain financing, and adoption of alternative credit scoring models to offer digital loans will be introduced. Among the initiatives,

the digital credit scheme will commence in December 2022, the cluster financing scheme in September 2022, and the value chain financing in June 2023.

<https://www.thedailystar.net>

### CHINA

#### Corporate R&D spending

Chinese corporates have boosted R&D expenditure in the past 2 years, as they strive to boost competitiveness and reduce reliance on imports, says Fitch Ratings. We expect spending to keep rising after the country highlighted R&D as a key national strategy in its 14th Five-Year Plan in May 2021. It has also introduced many favorable policies since 2H18, including a R&D super deduction before tax for corporates.

China's corporate R&D notably outpaced GDP in 2019–2020. The corporate R&D/GDP ratio rose to 1.84%, from 1.26% in 2010, increasing at a faster rate than at most developed countries. We believe the higher spending is partly in response to the increasingly intense US–China relationship, after the US imposed import tax on Chinese-made goods in July 2018 and launched a few entity lists against China's high-tech corporates and agencies since October 2019. Companies on the lists face export and other restrictions. This prompted Chinese corporates to reduce reliance on foreign suppliers, especially from the US and its allies.

R&D spending by central state-owned enterprises (SOE) rose by 11.3% yoy, to account for 49% of China's total corporate R&D in 2020, and boosted SOEs' aggregate R&D/revenue ratio to 2.6%, from 1.4% in 2018. This followed the introduction of R&D intensity in the key performance indicators set by the State-owned Assets Supervision and Administration Commission, which said central SOEs should treat scientific research spending as profit in their performance evaluations in early 2021. Growth in central SOEs' aggregate R&D further accelerated to 37.4% yoy in 1H21. Furthermore, Beijing issued Outline of Building a Powerhouse in Intellectual Property (2021–2035) in September

2021, a milestone policy for protecting intellectual property.

<https://www.fitchratings.com>

#### R&D spending

China's research and development (R&D) spending accounted for 2.4% of the country's aggregate GDP in 2020, not only recording a near decade high in growth but is quickly catching up with international standards, and in particular, the US, according to a statistical communique released by the National Bureau of Statistics along with two other government departments. Last year, China invested a total of 2.4 trillion yuan (\$372 billion) in R&D, up 10.2% compared with the previous year. The ratio between China's R&D and GDP output had risen by 0.16 percentage point compared with the year of 2019, the highest rate of growth in nearly 11 years.

The numbers also show that China is closing the gap with other countries including the US in terms of R&D input. According to data released by the Organisation for Economic Cooperation and Development (OECD), R&D spending in the US was about 3.07% of GDP in 2019. The OECD has not reported US' R&D spending for 2020. The NBS noted that in terms of total R&D input, China's R&D spending accounted for about 54% of US spending in 2020, while it was 2.1 times that of Japan. Currently, China's R&D spending ranks second globally. China's average yearly R&D input growth reached 11.8% between 2016–2019, significantly higher than the US' 7.3% and Japan's 0.7% growth.

The data is also a reflection of China's continued efforts to advanced high-tech growth despite the impact of the coronavirus, as the country has rolled out favorable policies, like improving tax exemptions for domestic research companies, that yield positive results for investment in innovation, the NBS noted.

<https://www.globaltimes.cn>

#### Intellectual property rights protection

Zhang Zhicheng, head of the protection department of China's National Intellectual Property Administration, confirmed

that an action plan for IPR protection of the two events has been initiated across the country. The plan aims to enhance the protection of Olympic symbols. It will also allegedly protect design patents and registered trademarks of Olympic symbols in line with the country's patent and trademark laws. Zhang claimed that the plan will help to improve the popularization of IPR protection involving Olympic symbols and raise legal awareness of IPR among the public.

The strategy focuses on IPR protection in areas such as commodity production bases, logistics distribution centers and e-commerce platform headquarters as well as promoting information sharing among related authorities. During the campaign, those who infringe patents or trademarks involving Olympic symbols will be harshly punished, Zhang said, adding that IPR-related inspections in places that produce or sell Olympic products as well as at e-commerce giants need to be intensified.

<https://www.insidethegames.biz>

### Solar subsidy

China has revealed its initial subsidy limits for existing renewables projects in 2022; however, it remains to be seen whether the funding is to be topped up. China's Ministry of Finance set out its first tranche of funding for existing renewable projects for the forthcoming year, making RMB3.87 billion (US\$607.3 million) available. Of that total, RMB2.28 billion (US\$357.2 million) has been set aside for solar PV projects, with RMB1.55 billion available for wind.

At RMB2.28 billion, the rate available in 2022 is a marked decrease—down 32.6%—on the RMB3.384 billion made available for projects last year. However, it is as yet unclear whether the finance ministry intends for this to be the full sum available in 2022 or whether the pot will be topped up at a later date.

A note issued by the finance ministry establishes the priority for subsidies to be paid by power grid companies in the country according to official fund man-

agement measures, as per the usual process. All funds are to be allocated to generators included in China's list of projects, with priority given to national PV projects that are alleviating poverty and so-called 'Top Runner' projects confirmed by China's central government. Half of the total subsidy payable to these projects is to be allocated by the end of this year. Other projects, including distributed systems up to and including 50 kW in size and projects determined by competitive bidding tendered by 2019 will have subsidy allocated proportionally.

<https://www.pv-tech.org>

## INDIA

### VC firms betting big on Web 3.0 startups

Indian venture capital firms are betting big on Web 3.0 startups as they view such companies as developers of products for the next stage of the internet, which is characterized by a decentralized online ecosystem based on blockchain technology. Early-stage Indian VC firm Antler India, a unit of Singapore-based venture capital platform Antler, has committed to invest in 25–30 startups in the blockchain and Web 3.0 space in the next 2–3 years. It plans to deploy \$100 million to \$150 million in over 100 Indian startups over the next 3 years, of which up to \$50 million is committed to the Web 3.0 space. The fund will make a minimum investment of \$250,000 and will come in at a pre-product market fit stage, Nitin Sharma, partner and global blockchain lead at Antler, told ET.

Sharma is also the founder of another VC fund, Incrypt Blockchain, as part of which he has invested in Mudrex, a social trading and decentralized finance (DeFi) aggregator, OnJuno, a payroll infrastructure bridging banking and crypto, among others. In an unprecedented year for the Web 3.0 space in India, Sequoia India has made about 20 investments in Web 3.0 startups including Betafinance, Clearpool, Coinshift, and Faze, through a combination of equity and token investments.

<https://www.google.com>

### 5G technology to be incorporated in global standard

In a major boost for the Department of Telecom, the made-in-India standard 5Gi is all set to be formally incorporated in the global 5G standard (3GPP). This will enable telecom equipment makers, especially the domestic players, to start using this standard to develop network gear for 5G services. According to sources, a formal agreement is expected to be announced in the coming week. The DoT has been coordinating with the global players for the incorporation of 5Gi with the 3GPP standard. 3GPP is an international body that defines the global standard for telecom sector. The new standard was developed under the supervision of Telecom Standard Development Society India and DoT with major contribution from all major IITs and IISc.

Some of the features of the 5Gi standard include enabling higher power for mobile phones. The handset power levels have been doubled under the harmonization of 5Gi with the global standard (increased from 23 dbm to 26 dbm). A modulation scheme, technically called pi/2 BPSK, which was earlier optional under the 3GPP standard, has now become mandatory. However, some other key features developed under 5Gi have not been incorporated by 3GPP, according to sources.

The key selling point of the standard is that it would be especially pertinent for local use, and bolster rural connectivity. It is also supported by Indian technology companies, including TCS, Saankhya Labs, HFCL, Tejas Network. The new standard could make their equipment more relevant for Indian 5G deployment.

A key win for the made in India standard is that the proposed features of 5Gi will now be globally deployed and implemented. Furthermore, any future development of 5Gi will happen under the aegis of 3GPP, which means 5Gi is unlikely to be deployed independently. Thus the concerns of MNCs such as Nokia, Ericsson as well the operators-Bharti, Reliance Jio and Vodafone Idea, that standalone

deployment of 5Gi would fragment the ecosystem, are abated.

Without global standardization, there would have been an additional burden of testing all elements of the infrastructure and devices for various networks. "In this globalised world standardization and interoperability is the key to driving economies of scale and faster deployment. Otherwise, you have another TDS CDMA or FOMA story, where technologies did not go anywhere due to the lack of standardization," said an industry expert.

<https://www.google.com>

## MALAYSIA

### Startup ecosystem roadmap

The Ministry of Science, Technology and Innovation (Mosti) is targeting to build a conducive startup ecosystem with the launch of the Malaysian Startup Ecosystem Roadmap (SUPER) 2021–2030 and the MYStartup platform. In a statement, Mosti said SUPER is a plan to develop a dynamic national startup ecosystem and in line with Vision 2030. MYStartup is a digital information resource portal that provides comprehensive facilitation services for startup ecosystem networks, it said.

Mosti said SUPER is designed to increase the nation's gross domestic product (GDP) and is expected to contribute to high-value job creation as well as expanding deep technology investments by 2030. The development of SUPER has taken into account feedback from over 300 startup ecosystem stakeholders, it said. Mosti said SUPER is for all including government, investors as well as innovators to achieve the ultimate goal of placing Malaysia as one of the Top 20 global startup ecosystems.

Meanwhile, the MYStartup platform is a national digital portal of information resources aimed at helping ecosystem players navigate the startup ecosystem and drive local innovation, Mosti said. It will also assist and guide developing startups that have world class investment value.

<https://www.digitalnewsasia.com>

## PHILIPPINES

### Renewable energy roadmap

Philippines' proposed National Renewable Energy Program (NREP) 2020–2040 is setting a target of 35% share of renewable energy (RE) in the power generation mix by 2030 and 50% share by 2040. This was shared by Director Mylene C. Capongcol, OIC of the Department of Energy's (DOE) Renewable Energy Management Bureau, who in a recent online presentation acknowledged that instead of growing, the share of RE in the power generation mix has actually declined. She noted that in 2008, the year the Renewable Energy Act was passed, the share of RE was about 34%. Now it is down to 21%, or 21,609 gigawatt-hours (GWh), out of a total 101,756 GWh of power generated. The government is looking to revert the share of RE to 35% by 2030 and 50% by 2040 under the updated NREP, Capongcol said.

The NREP sets the roadmap for achieving the country's RE goals as required by the Renewable Energy Act of 2008. Republic Act No. 9513, or the Renewable Energy Act, provides the framework for the development, utilization, and commercialization of RE sources, defined as resources that can be replenished regularly and are available indefinitely. These include biomass, solar, wind, geothermal, ocean energy, hydropower, and other emerging RE technologies.

The Act affirms the government's commitment to accelerate the utilization of RE resources in the country to reduce harmful emissions and achieve economic development while protecting the health and environment. The transition to RE from carbon-intensive energies has become even more urgent in light of the massive destruction being wrought by climate change and uncontrolled greenhouse gas emissions not just in the country but on a global scale.

<https://www.pna.gov.ph>

### Funding for research and development

There is a record-breaking increase in human and financial resources support-

ing research and development (R&D) from 2015 to 2018, a study by the Department of Science and Technology (DoST), the Philippine Statistics Authority and the University of the Philippines Los Baños showed. DoST Assistant Secretary for Finance and Strategic Planning Maridon Sahagun reported that the number of R&D personnel has tripled, from a headcount of 25,000 in 2015 to 75,000 in 2018.

Sahagun said that in 2018, 46% of R&D personnel in the country were working in higher education institutions (HEIs), 72% of which were state-run; 18% were in government, and 2% were part of private non-profit institutions. "Half of the R&D personnel in the Philippines in 2018 are researchers, one-third are auxiliary personnel, and the remaining 16% are classified as technicians," she said.

The National R&D expenditure, also known as the gross expenditure on R&D (GERD) more than doubled, from P21.9 billion in 2015 to P58.9 billion in 2018. Sahagun noted that the ratio of GERD to the gross domestic product jumped from 0.16% to 0.32% within the 3 years. The majority of R&D spending came from the private industry at P31.6 billion, followed by the government (P13.5 billion), HEIs (P11.8 billion), and private non-profit institutions (P1 billion).

The agency also launched its 2019–2020 survey on R&D expenditures and human resources to look into how the pandemic has affected the country's R&D spending and employment of personnel in the field of S&T.

<https://www.manilatimes.net>

### R&D inclusive growth

A strong and purposeful research and development (R&D) programme is a crucial factor in a country's long-term growth. R&D is also essential to the advancement of society. It offers scientific knowledge for the creation of new products, solutions, and services. While it necessitates significant investments and a great deal of patience, the rewards are substantial. Policymakers and researchers are realizing that R&D is a critical component for

increased productivity, competitiveness, and well-being. Moreover, it has the potential to address some global issues such as climate change and public health.

The Republic Act 11293 or the Philippine Innovation Act is said to bolster the government's R&D efforts. The National Economic and Development Authority had developed the implementing rules and regulations in collaboration with the Departments of Science and Technology and Trade and Industry.

The Department of Trade and Industry (DTI) recently announced plans to expand access to research and development (R&D) across the country at a recent event. In his message to the ASEAN Summit on Spin-Off Technologies, the DTI Secretary mentioned that the agency is organizing Regional Inclusive Innovations Centres (RIICs) across the country to democratize the growth of startup communities.

He noted that R&D is the "true heart" and "DNA" of entrepreneurship and that making it more inclusive will enable more startup communities and support young entrepreneurial talents in technology and creative industries. Micro, small, and medium-sized enterprises (MSMEs) can use the RIIC to position their products in the global value chain, giving them a competitive advantage in the global market.

<https://opengovasia.com>

### Energy Option Program

The Independent Electricity Market Operator of the Philippines (IEMOP) launched the Green Energy Option Program or GEOP, December 3, 2021. This is following the Energy Regulatory Commission's issuance of ERC Resolution No. 08, Series of 2021. GEOP is one of the various programs under the Renewable Energy Act of 2008 which aimed to promote the development of renewable energy in the country. The program provides consumers an option to source their electricity supply from renewable energy resources, such as biomass, solar, wind, geothermal, ocean energy, and hydropower. Under the regulation, those with average peak electricity requirements equal to or greater

than 100 kW are the first set of consumers that can benefit of the GEOP program. Consumers of electricity are no longer constrained to only source their electricity supply from the distribution utility of their location.

Eligible consumers may now choose from various "Renewable Energy Suppliers" that are authorized by the DOE to procure energy from renewable energy facilities. Through such mechanism, GEOP aims to contribute to energy sustainability and promote further competition in the electricity sector.

<https://www.thinkgeoenergy.com>

## REPUBLIC OF KOREA

### Multinational drugmakers' R&D

Global pharmaceutical companies' investment in R&D in the Republic of Korea has continued to rise for the fifth consecutive year in 2020, an industry group report showed. The number of early clinical trials and studies of cancer and rare diseases increased significantly, and employment for R&D also expanded steadily, the report said. Korean Research-based Pharmaceutical Industry Association (KRPIA) released its report on 31 members' expenses for local R&D and researchers. The KRPIA's survey was jointly conducted by a research team led by professor Shin Ju-young of Sungkyunkwan University's School of Pharmacy.

The report showed that 31 multinational drugmakers spent 569.3 billion won (\$478.9 million) on clinical research in the Republic of Korea in 2020. The costs excluded R&D expenses commissioned directly by their global headquarters. Despite the ongoing Covid-19 pandemic, multinational pharmaceutical firms continued to contribute to the Republic of Korean economy through increased R&D activities, KRPIA said.

Based on data from 25 KRPIA members that participated in the survey for the past 5 years since 2016, the total R&D spending increased from 360 billion won in 2016 to 590.2 billion won in 2020. Compared to 2019, the R&D jumped by 114.2 billion

won (24%) in 2020. The 31 multinationals had 1,846 employees for R&D activities in 2020. They conducted a total of 1,499 clinical trials in 2020. Based on data from 25 KRPIA members between 2016 and 2020, the 25 firms worked on approximately 1,200 studies. In 2020, the number of phase 1 and phase 2 trials increased faster than phase 3 trials.

"Member companies not only invest in R&D through clinical trials but support basic research (three cases), non-clinical trials (four cases), an introduction of locally developed substances, a joint development with domestic pharmaceutical companies and research institutes, and R&D with local hospitals and organizations (12 cases)," an official at KRPIA said. Also, he added that KRPIA ran 15 programs to provide education for local universities and research institutes so that the Republic of Korea could have a better capability for new drug development and harmonize with the international standards.

The total value of investigational drugs, provided for domestic patients for free in clinical trials, was estimated to be 226.6 billion won in 2020, based on data from 31 KRPIA members, KRPIA said. Clinical trials for cancer and rare disease treatment accounted for 64.5% (780 cases) and 10.3% (125 cases). Seventeen studies aimed to develop a Covid-19 treatment or a vaccine.

According to the KRPIA official, the Republic of Korea registered the second-largest clinical trials in East Asia, after China. However, Korea's share in global clinical trials went down from 2017 to 2019 but rose again in 2020 to rank at the world's sixth, up by two notches from 2018, he went on to say. He said this was attributed to the Republic of Korean government's deregulation efforts, including the 5-year national project to advance clinical trials.

<https://www.koreabiomed.com>

### Tax incentives, R&D spending on battery sector

The Republic of Korea said it will increase investment to develop the next-generation battery technology, expand its manufac-

turing base and secure supply chains as it seeks to foster the rechargeable battery industry as the next growth driver. The Ministry of Trade, Industry and Energy unveiled the so-called K-battery blueprint to solidify the nation's battery leadership as major economies are racing to develop their own supply chains to benefit from the fast-growing electric vehicle market.

The Republic of Korea accounted for 44.1% of the global rechargeable battery market last year ahead of China and Japan, led by small batteries for IT devices and medium-sized and large batteries for EVs, according to the ministry. While the nation's battery trio—LG Energy Solution Ltd., Samsung SDI Co. and SK Innovation Co.—accounted for a third of the global EV battery market in 2020, calls for broader support have risen to better compete with Chinese rivals that have expanded their presence on their home turf, the world's top EV market.

"The global competition for rechargeable batteries has just begun in earnest as the U.S., Europe and China are stepping up efforts to secure the manufacturing base, battery technology and supply chains to target the rapidly growing market," the ministry said in a release. "The government has come up with the comprehensive battery policy to make concerted efforts with the private sector as the global battery race will face a critical juncture in the next 5 years."

Under the battery road map, the nation's battery makers and related firms will receive up to a 50% tax discount for R&D spending and 20% of tax cuts on facility investment.

The ministry said it aims to nearly triple battery exports from \$7.5 billion in 2020 to \$20 billion by 2030, as the nation's three battery makers have vowed to invest a combined 40 trillion won (US\$35.3 billion) over the next decade.

While lithium-ion batteries currently dominate the EV battery market, the ministry said it will collaborate with the battery manufacturers and related agencies to develop next-generation batteries with enhanced energy efficiency, longer range and safety. For example, the country will seek the

commercialization of the solid-state battery, which is considered a safer and more energy-efficient option for EVs, by 2027.

The Republic of Korea also plans to develop a lithium-sulfur battery, which is more competitive in terms of weight, for drones and aircraft by 2025. The government also vowed to cooperate with the private sector to enhance lithium-ion batteries' capacity and safety via R&D projects aimed at improving the chemistry mix and cell structure.

The ministry said it will build "the next-generation battery park" by 2026 to facilitate local firms' research and test efforts, and create an 80 billion-won fund jointly with the three battery makers to support R&D projects. It also plans to step up efforts to help local companies secure key resources for battery materials and explore ways to reuse materials from spent batteries to cope with possible global shortages of raw materials.

<https://m-en.yna.co.kr>

### Action plans for carbon neutrality

The Republic of Korea will close down 24 aging coal-fired power plants permanently by 2034 as part of efforts to phase out coal consumption for electricity generation by 2050 and boost the country's clean hydrogen self-sufficiency ratio to 34% in 2030, and further to 60% in 2050, the government said December 10. The government unveiled the country's first detailed "action plans" to achieve a carbon neutrality under which the Republic of Korea also plans to use carbon-free sources of ammonia and hydrogen as a key power generation fuel to reduce coal and LNG demand for electricity production.

The action plans, which were announced jointly by 10 related government agencies, such as the industry-energy ministry, the economy-finance ministry, the environmental ministry and the science ministry were focused on an early requirement of coal-fired power plants. "A total of 24 aging coal-fired power plants will be fully retired by 2034 and operation of the other coal power plants will be restricted, which will

lead to no coal-based electricity generation by 2050," the joint statement said.

The country is currently running 53 coal-fired power plants as seven have been permanently closed down for the past 2 years as part of President Moon Jae-in's push to reduce the country's heavy reliance on coal in power generation and address worsening air pollution. "The government plans to raise the portion of ammonia to 3.6% in 2030, or 22.1 TWh, in 2030 compared with zero currently," said an official at the Ministry of Trade, Industry and Energy.

In addition, South Korea will provide 27.9 million mt/year of "clean hydrogen" by 2050, green or blue hydrogen, including imports of 22.9 million mt/year of green hydrogen from overseas, the official said. "Under the action plans, the combined portion of renewable and carbon-free sources will rise to 33.8% in the country's power generation mix in 2030, compared with 6.6% in 2020, and will further jump to 93.6% in 2050," the government statement said. "As nuclear reactors will account for 6.1% in 2050, 99.7% of South Korea's power generation will come carbon free," it said.

The country will also secure 900 million mt/year of carbon storage space by 2030 to make sure there are no carbon emissions by 2050, according to the general strategy. The government is also pushing to enact a "basic law on resources security" so as to secure stable supplies of hydrogen, ammonia and renewable sources in addition to oil and gas. With the action plans in place, the shares of coal and LNG in power mix will be reduced to 21.8% and 19.5% in 2030, respectively, from 35.6% and 26.4% in 2020, before being phased out in 2050. "With the measures, carbon emissions by the industrial sector will be slashed to 226.6 million mt in 2030, and further to 51.1 million mt in 2050, down 80.4% from 260.5 million mt in 2018," the joint statement said. In an initial stage, the government and businesses will spend Won 90 trillion (\$76.3 billion) over the next 4 years until 2025 in carbon reduction projects, the statement said.

<https://www.spglobal.com>

## THAILAND

### Incentives for R&D, semiconductors, smart packaging

Thailand has released new incentives for investments in research and development (R&D), semiconductor manufacturing, smart packaging, and other digital technologies, as the government seeks to capitalize on soaring global demand for products in the sector due to supply chain disruptions caused by COVID-19. Thailand's Board of Investment (BOI) approved the incentives at a meeting on June 30, 2021.

Thailand is already a major player in South-east Asia's semiconductor industry, which analysts expect to grow rapidly in the coming years. The market research firm Fortune Business Insights projects ASEAN's semiconductor market to grow at a compound annual growth rate of 6.1% from 2021 to 2028, rising from US\$26.9 billion in 2020 to US\$41.9 billion by 2028.

The R&D and human resource (HR) incentives apply to companies making large investments in innovation. Eligible companies will benefit from extended tax holidays lasting up to 13 years without a corporate income tax exemption ceiling. In other words, these companies will be exempt from Thailand's headline corporate income tax rate of 20%.

To qualify, companies must invest a minimum of 200 million baht (US\$6.1 million) or 1% of their total sales in their first 3 years on R&D activities. The exact length of the extended tax holiday depends on the amount the company invests in R&D.

Further, companies that adopt apprenticeship programs or invest in advanced technologies will be eligible for similar incentives. For example, semiconductor projects with additional investments in R&D may be eligible for a tax exemption of up to 5 years.

Moreover, companies hiring Thai workers for software development, digital services platforms, or digital content may qualify for a tax holiday of 8 years. The corporate income tax exemption ceiling for

this incentive depends on the number of Thai workers hired for these roles, as well as associated expenses for training and acquiring international certifications.

In addition to the R&D and HR development incentives, the BOI approved measures to promote investment in manufacturing, with a focus on semiconductors. Per the BOI's incentives, front-end capital and technology-intensive manufacturing will be given tax holidays for 10 years. This includes front-end semiconductor investments, such as in electronics design, silicon wafers, and wafer FAB.

Back-end semiconductor investments, such as in wafer SORT, die bank, assembly, and integrated circuit testing, qualify for tax holidays of 8 years with machinery investments of at least 1.5 billion baht (US\$45.7 million), and 5 years with machinery investments below 1.5 billion baht (US\$45.7 million).

Machinery investments worth at least 1.5 billion baht (US\$45.7 million) in the advanced printed circuit board (PCB) manufacturing are eligible for tax holidays of 8 years, while investments worth less than 1.5 billion baht (US\$45.7 million) qualify for tax holidays of 5 years. Finally, machinery investments in printed circuit board assembly (PCBA) worth at least 500 million baht (US\$15.2 million) can enjoy a 5-year tax holiday. Investments worth least than 500 million baht (US\$15.2 million) may qualify for a 3-year tax holiday.

The BOI also approved incentives for companies producing smart and environmentally friendly packaging, in line with the government's Bio-Circular-Green (BCG) model. Smart and environmentally friendly packaging includes digitally enabled packaging and packaging made from recycled materials, among others. Companies manufacturing active and intelligent packaging may qualify for tax holidays of 8 years. Active packaging refers to packaging that maintains the quality of the product, while intelligent packaging refers to packaging that can sense the quality of the product.

Further, companies creating smart packaging or parts thereof may be eligible for

a tax holiday of 3 years. Smart packaging refers to packaging made from "special substances".

## VIET NAM

### New regulations on medical device management

On November 8, 2021, the Vietnamese government issued Decree No. 98/2021/ND-CP on the Management of Medical Devices ("Decree 98"). The new decree will take effect from January 1, 2022, replacing Decree No. 36/2016/ND-CP and its amendments on the same subject ("Decree 36"). Below are the main highlights of Decree 98:

#### 1. Classification of medical devices

Under Decree 98, responsibility for the classification of medical devices is given to the organization registering or declaring the medical device. Under Decree 36, this responsibility was reserved for Vietnamese organizations qualified for medical device classification.

#### 2. Clinical trials of medical devices

Decree 98 provides stricter and more detailed requirements on clinical trials. Particularly, medical device trials will include three phases, in which phases 1 and 2 need to be finished before the product registration, while phase 3 will be conducted after the medical devices are approved for circulation, following the specific requirement from the authorities. This requirement aims to continue evaluating the safety and efficacy of medical devices after they are widely used in the community in line with their usage conditions.

#### 3. Medical device registration

Similar to the current regulations, Decree 98 requires that medical devices must be registered with the Vietnamese authority (i.e., must obtain registration numbers) before being imported/manufactured for circulation in the Vietnam market. However, Decree 98 further stipulates new requirements as below.

##### *Validity of registration numbers*

Under Decree 98, the registration numbers for all classes of medical devices, not only

Class A medical devices as in the current regulations, are valid indefinitely, except for registration numbers granted under the emergency registration procedure.

#### *Registration procedure for Class A/B medical devices*

Instead of having to register with the central level authority with a complex registration dossier as currently required, Decree 98 allows Class B medical devices to be subject to a simpler registration procedure, namely, "Declaration of applied standard" with the provincial level authority, which is the same procedure as for the lowest risk Class A devices.

#### *Registration procedure for Class C/D medical devices*

For the first time in Vietnam, Decree 98 sets out three procedures to apply for registration of Class C/D medical devices: the normal registration procedure, a quick registration procedure, and an emergency registration procedure.

The Ministry of Health's evaluation timeline for handling registration dossiers for Class C/D medical devices under the normal procedure will be up to 45 days, while the timeline under the quick and emergency procedures will be only 10 days.

#### **4. Price management**

In an effort to control the price of medical devices, Decree 98 includes a new requirement in which registration number holders must declare the prices of their medical devices on the Portal of Medical Device Management before putting the medical devices on the Vietnam market; the actual prices must not be higher than the declared prices. The authorities may question the registration number holder about grounds for the declared prices at any convenient time.

#### **5. Importation of medical devices**

Decree 98 sets out situations where medical devices without registration numbers must have import licenses. These include, among others, medical devices for scientific research, tests, trials, quality assessment, or training; medical devices for aid, humanitarian aid, gifts, fairs, exhibitions, displays, or product introduction; and

medical devices meeting urgent needs for national defense, security, epidemic prevention and control, and overcoming consequences of natural disasters and catastrophes.

#### **6. Medical device advertisement**

Decree 98 completely removes the procedure for approval of medical device advertising contents. Instead, the holders of medical device registration numbers or their authorized entities will be responsible for publicly declaring the intended content and form of the advertising on the Portal of Medical Device Management before conducting the advertising.

#### **7. Transitional regulations**

Decree 98 sets out the following transitional mechanisms:

- Medical devices produced/imported into Vietnam before January 1, 2022, may be continuously circulated until they are liquidated as stipulated or until their expiry date.
- For import licenses/registration numbers granted before January 1, 2022:
  - Registration numbers granted under Decree 36 and its amendments will be valid indefinitely.
  - MAs granted to domestic medical devices will be valid until their expiry date.
  - Import licenses for medical devices that were granted from January 1, 2018, will be valid until December 31, 2022. Import licenses for medical devices that are IVD biologicals will have no limit on quantity.
  - For Class C/D medical devices that are not subject to import licenses and whose classification results were published on the Portal of Medical Device Management, they can be continuously imported until December 31, 2022, with no limit on quantity and without an approval letter from the Ministry of Health.
  - MAs for medical devices that are IVD biologicals that were granted from January 1, 2014, will be valid

until December 31, 2022, or their expiry date, whichever is later.

- For registration dossiers prepared and submitted in line with Decree 36 but for which registration numbers have not yet been granted as of January 1, 2022:
  - For Class B medical devices, the registrant should conduct the (simpler) procedure for declaration of applied standard with the Department of Health under Decree 98; the governmental fee will be waived.
  - For Class C/D medical devices, if the submitted dossiers comply with Decree 98, they will be reviewed and granted registration numbers in line with Decree 98.
  - Classification certificates issued by local organizations qualified for medical device classification before January 1, 2022, can continue to be used in registration dossiers.
- Registration dossiers for obtaining import licenses submitted before January 1, 2022, will continue to be reviewed and handled in line with current/old regulations. These import licenses will be valid until December 31, 2022.
- From January 1, 2023, it will be required to apply the Common Submission Dossier Template (CSDT). Registration dossiers submitted before December 31, 2022, may submit documents including (i) technical summary, (ii) Instructions for use and (iii) label intended for Vietnam market instead.
- The declaration of advertising content for medical devices will be applied from July 1, 2022.
- Holders of registration numbers or import licenses granted before January 1, 2022, must take responsibility for price declaration under Decree 98 before April 1, 2022, for medical devices that are circulating in the Vietnam market and before putting medical devices on the Vietnam market for the first time.

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