HANKUN
汉坤律师事务所
Han Kun Law Offices

Han Kun Newsletter

Issue 193 (5th edition of 2022)

Legal Updates

1. ESG Investment Trends and Outlook - the Perspective of Fund Managers and Long-term Investors
2. New LDT Pilot Regulations Key Takeaways

1. ESG Investment Trends and Outlook - the Perspective of Fund Managers and Long-term Investors

Authors: Yin GE | Virginia QIAO | Lin ZHU | Avery HUANG | Mark MAO[1]

As sustainable development and social responsibility are increasingly stressed in the business community, major institutional investors have come to focus on environmental, social, and governance (ESG) investing, an approach that directs socially responsible investment decisions. While the concept of ESG investing originated in the West and has evolved into a mainstream investment philosophy in overseas markets, we have noticed that an increasing number of PRC fund managers and long-term investors have developed a keen interest in ESG and are eagerly planning their next moves. Their investment philosophies have also steadily shifted from "passive compliance" to "active empowerment". This newsletter provides an overall analysis of the ESG regulatory framework and investment practices in China, followed by an outlook for the future trends in ESG investing from the perspective of fund managers and long-term investors.

Part I ESG regulatory framework and investment practices

Current ESG regulatory framework in China

ESG regulations in China are being continually explored, but no uniform or explicit regulatory standards have yet taken shape. On the whole, the People's Bank of China, the China Banking and Insurance Regulatory Commission ("**CBIRC**") and the China Securities Regulatory Commission ("**CSRC**") (collectively, the core financial regulators; the CBIRC was absorbed by the National Administration of Financial Regulation on May 18, 2023, a new core Chinese financial regulator), along with the National Development and Reform Commission ("**NDRC**"), have issued policies to support the development of green finance/ESG and the offering of relevant financial products, and set out regulatory requirements for listed companies and enterprises that offer green bonds. On this basis, securities offerings and trading venues such as stock exchanges and the National Association of Financial Market Institutional Investors have issued detailed regulations for ESG-related securities offerings and information disclosure. In addition, the Asset Management Association of China ("**AMAC**") and other similar industry self-regulatory organizations have formulated rules overseeing ESG investment within their respective industries.

From the perspective of fund managers and long-term investors, current ESG regulations in China concentrate on the following two dimensions:

I. Rules to regulate ESG investing activities

1. Disclosure requirements on investee companies

The earliest ESG regulatory move in China may date back to 2006, when the Shenzhen Stock Exchange issued its *Social Responsibility Instructions to Listed Companies*. These instructions were followed by requirements for ESG-related disclosure of listed companies released by the CSRC and

[1] Han Kun intern Xiao LIANG also contributed to this legal commentary.

stock exchanges, which form the main body of currently effective ESG-related rules for securities issuers. Information disclosed pursuant to those rules have provided valuable references to fund managers and long-term investors in their ESG investment research and asset allocation decisions.

2. ESG-related regulatory policies

While a series of ESG-related policy documents have been issued and serve as the key drive of ESG investing in China, these policies tend to be regarded merely as concepts and await broader implementation. One example is the CSRC's promise of preferential treatment to investors as incentives for them to act on the government's environmental and social initiatives, such as poverty alleviation. In its *Guiding Opinions on Supporting the Development of Green Bonds*, the CSRC encourages fund management companies, private fund management institutions, and the products under their management to invest in green corporate bonds. The CSRC also grants accelerated procedures for the registration of products issued by private fund managers that play an active role in poverty relief, as prescribed in the *CSRC Opinions on Giving Play to the Role of Capital Markets in Supporting China's National Poverty Alleviation*.

3. Obligations to report on investment practices

Currently effective rules stipulating reporting obligations tend to focus on the reporting of green investment practices and are silent on the social and corporate governance aspects of ESG. Notably, according to AMAC's *Green Investment Guidelines (for Trial Implementation)*, managers of publicly and non-publicly offered securities investment funds or asset management plans are required to conduct an annual self-assessment of their green investment practices and report on the same to the AMAC[2]. Pursuant to the Guidelines, the AMAC will also carry out spot checks on green investment practices of fund managers on an irregular basis.

II. Internal ESG system construction for fund managers

1. Mutual fund managers

Mutual fund management companies attach greater importance to structuring their internal ESG systems in compliance with regulatory requirements, with special focus on applying ESG at the internal organization level and the corporate governance level, and on fulfilling corporate social responsibilities. Key measures to realize the above goals include setting up an internal body in charge of the company's social responsibility activities, overall planning of ESG construction schemes, reforming social responsibility plans, as well as measures such as improving internal controls, combatting money laundering, and promoting employment.

2. Private securities investment fund managers

Compared with mutual fund managers, private securities investment fund managers are smaller in terms of the company size and number of employees, thus are more flexible regarding organizational

[2] The AMAC has released its yearly Report on Fund Manager Green Investment Self-assessment for the 4th consecutive year based on the self-assessment reports and self-assessment forms submitted by fund managers. The Reports are available at https://www.amac.org.cn/businessservices_2025/ywfw_esg/esgyj/.

structure and corporate governance.

ESG regulation in China is still in its infancy and without a fully-fledged supervisory framework. First, regulators have not clearly defined the meaning of an ESG product, as well as its extension, which is essential for further improving the ESG regulatory framework. Also, ESG disclosure requirements for investees, especially unlisted bond issuers, need to be further refined, and uniform criteria and standards should be specified regarding information disclosure of listed companies, which currently vary in practice.

ESG in overseas markets

According to Morningstar, an authoritative international fund ratings agency, global ESG fund assets hit USD$2.5 trillion at the end of 2022 and attracted USD$37 billion in the fourth quarter of 2022[3]. Bloomberg Intelligence, a world-renowned industry insights provider, predicts that global ESG assets may surpass USD$50 trillion by 2025, one-third of the projected total assets under management (AUM) globally[4].

I. ESG investing strategies

In its global review, the Global Sustainable Investment Alliance (GSIA) divides ESG investing strategies into seven categories: (1) **negative/exclusionary screening;** (2) **positive screening/best-in-class;** (3) **norms-based screening;** (4) **ESG integration (inclusion of ESG factors into financial analysis);** (5) **sustainability themed/thematic investing;** (6) **impact investing; and** (7) **corporate engagement & shareholder action (employing shareholder power to influence corporate behavior and engage in corporate management)**. Given the status quo of mutual funds and ETF funds issued by overseas asset managers, ESG investment in the US mainly adopts exclusionary screening and positive screening in the broader market, as well as the more targeted approaches of thematic investing and impact investing.

II. ESG regulation

As to ESG regulation in the global market, multiple sets of ESG asset certification standards have been issued by international organizations; also, the ESG disclosure regime in Europe tends to be more fully developed, covering a full range of environmental, social, and governance metrics, and is currently considered one of the most stringent ESG disclosure frameworks in the world. The EU ESG regulatory framework is composed of the EU Taxonomy Regulation, the Corporate Sustainability Reporting Directive (CSRD), and the Sustainable Finance Disclosure Regulation (SFDR), among which the SFDR, as the fundamental pillar of the EU ESG regulatory framework, applies to the bulk of financial institutions that operate in the EU market, with a main focus on asset management companies.

[3] *Morningstar: Global Sustainable Fund Flows: Q4 2022 in Review* https://assets.contentstack.io/v3/assets/blt4eb669caa7dc65b2/blt7df82e5b9c6a5528/63d40a22f1b8c22282814816/Global_ESG_Q4_2022_Flow_Report.pdf.

[4] *Bloomberg: ESG May Surpass $41 Trillion Assets in 2022, But Not Without Challenges, Finds Bloomberg Intelligence* https://www.bloomberg.com/company/press/esg-may-surpass-41-trillion-assets-in-2022-but-not-without-challenges-finds-bloomberg-intelligence/.

ESG practices in China's financial and asset management markets

I. Domestic mutual funds

1. Overall direction and strategy of ESG investment

China's domestic ESG themes tend to revolve around local development in the country. According to AMAC's 2022 Mutual fund Industry Social Responsibility Report issued in February 2023[5] as well as our observations of ESG-themed fund practices in China, fund managers tend to focus on the following aspects and indicators when comprehensively evaluating potential investee companies: **Environmental** factors, such as low-carbon plans, environmental certification, and environmental violations; **social** factors, such as the quality of CSR reports, operational and safety incidents, employee growth rates, remuneration levels, poverty relief and donations, and negative events of relatively large impact on public opinions; **governance** factors, such as board independence, related-party transactions, financial credibility, encumbrance risks, violations of listed companies and/or their subsidies, and violations by senior executives and/or shareholders. These indicators are weighted to comprehensively evaluate a company's ESG performance, and companies achieving a rating above a defined threshold are selected as potential investees.

2. Investment targets of ESG products

Statistics show that green investment and socially responsible investing (SRI) are the main focus of ESG products in China. According to the AMAC's 2022 Mutual Fund Industry Social Responsibility Report[6], investees' social responsibility performance is a consideration for 79.17% of mutual fund managers in their investment decisions, and the fund industry as a whole tends to have deeper SRI engagement. As for green investment, according to AMAC's 2022 Report on Fund Manager Green Investment Self-assessment, released in December 2022[7], 87.0% of mutual fund institutions have embarked on green investment research while 71.7% have issued products targeting green purposes (only green investment products launched in China were considered for these statistics).

3. Evaluation mechanism of ESG investment

Mutual fund institutions have explored the market relatively deeply with respect to ESG investing practices. The 2022 Report on Fund Manager Green Investment Self-assessment[8] shows that about one third of mutual fund institutions have established their own green or ESG evaluation systems and data platforms that are both consistent with international standards and compatible with China's domestic market. The systems combine quantitative and qualitative analysis approaches and are comprehensively integrated in the institutions' investment research and decision-making processes. For example, it has been a common investment strategy of those institutions to combine negative/exclusionary screening with positive/best-in-class screening in their green performance

[5] The AMAC's 2022 Mutual Fund Industry Social Responsibility Report, available at: https://www.amac.org.cn/industrydynamics/guoNeiJiaoLiuDongTai/jjhywhjs/shzr/202212/t20221219_14294.html.

[6] Ibid, 5.

[7] The AMAC's 2022 Report on Fund Manager Green Investment Self-assessment, available at: https://www.amac.org.cn/businessservices_2025/ywfw_esg/esgyj/.

[8] Ibid, 7.

evaluation of listed investees based on information about the investees' pollutant discharge, carbon emissions, green income, capacity, etc. collected on their own or purchased from a third party.

4. ESG investment risk management mechanisms

Mutual fund managers are also working to build up mechanisms to better monitor and respond to environmental risks. For example, with respect to emergency response, classification-based risk control options such as risk alerts, sale of shares, trade restrictions, and inclusion into negative lists, are available and can be triggered based on the result of environmental risk assessment. Procedurally, in a mutual fund institution, risk alerts are normally sent by the risk management department or research department, before the relevant trading teams take specific measures in response. While not common, some institutions have established mechanisms such as an ESG committee, an investment committee, or a multi-department meeting to decide on the approach to cope with major environmental risks.

II. Domestic private funds

Although private securities investment fund managers in China started later than their Western peers, they are growing at an accelerated pace and showing great potential for development.

1. The overall status quo

Based on our observation of current market practices, when it comes to ESG investment, private fund managers tend to "keep an eye on the market without much engagement". Among the 320 sample private fund managers whose green investment self-assessment results are collected and analyzed in AMAC's 2022 Report on Fund Manager Green Investment Self-assessment[9], only 3.1% (10 of the 320) ever issued products for green investment purposes (only green investment products launched in China were considered in these statistics), while 17.2% (55 of the 320) have explicitly incorporated green investment into their corporate-level strategy.

Nevertheless, the above figures do not mean that private securities investment fund managers are not agile with ESG investment trends, as the above report also indicates that 74.1% (237 out of 320) of the sample managers have embarked on green investment research and the number of companies with in-house researchers is much greater than those with part-time researchers. Also, 84.1% (269 out of 320) of sample managers have senior executives or corporate-level committees in charge of green investment business. The year 2022 has witnessed a growing number of private securities investment fund managers engaging in green investment practice, as well as continuous improvement in the quality of green investment practices.

2. Key industries

When it comes to ESG investment, private fund managers pay special attention to certain industries such as industries related to climate change, carbon emissions (wind power/PV/energy storage), new energy vehicles, and those along the relevant industrial chains.

[9] Ibid, 7.

Part II The prospect and future trends of ESG investment

Policies and regulations

At present, overseas markets such as the EU, the US, and Hong Kong have gradually developed a three-in-one ESG investment system, with ESG information disclosure as the regulatory focus, an ESG rating system as a provider of specific methodology, and both working together to provide investment guidelines[10].

The Corporate Sustainability Reporting Directive (CSRD) was officially adopted by the EU Council on November 28, 2022, and has become the core EU legislation governing corporate ESG disclosures. With respect to the Chinese market, however, one of the main obstacles to the development of ESG investing is the lack of normative ESG disclosure rules, which hinders decision makers from effectively accessing ESG-related information; also, the absence of an indicator system and evaluation methodology that are well recognized and popularized in the market prevents fund managers and investors from carrying out effective evaluation and taking actions in response after obtaining ESG information. Given that, international institutions are still seeking to localize international ESG rating standards in China by taking into account local factors, so as to formulate an information collection model and indicator and evaluation system that are more applicable to the Chinese market, which will play a significant role in promoting ESG investment in China[11].

Market participants

I. The opening-up of the financial sector

Foreign-invested institutions have extensive experience in ESG practice, and with more sophisticated business development of foreign-invested asset management institutions in China there is a growing effort to import overseas ESG investment experience into the Chinese market.

We also find in practice that, for companies making cross-border investments, having an ESG edge can not only reduce the cost of capital of the company and alleviate its financing limitations, but also enhance the advantage of foreignness by flexibly leveraging its strengths in the social and governance metrics when adapting to various ESG standards in different host countries[12].

1. Foreign-invested mutual fund managers

On March 3, 2023, AllianceBernstein Fund Management received CSRC approval to become the eighth wholly foreign-owned mutual fund management company to carry out business in China. Also, on March 27, 2023, the CSRC officially accepted an application filed by Allianz Global Investors GmbH (owned by the Allianz Group) to operate a mutual fund business in China, meaning that another wholly foreign-owned mutual fund manager is expected to enter the Chinese market.

- Recently, Neuberger Berman Fund Management (China) Co., Ltd., a mutual fund company wholly

[10] *How to Develop a Well-regarded ESG Rating System*: https://m.thepaper.cn/baijiahao_21419113.

[11] Ibid, 10.

[12] Study of Economics (3rd Issue of 2022): Content and Abstracts - Institute of Economics, Chinese Academy of Social Sciences: http://ie.cass.cn/journals/economic_research_journal/contents/202206/t20220607_5411490.html.

owned by Neuberger Berman, announced that it has become the 45th signatory to the Green Investment Principles for the Belt and Road Initiative, and the first mutual fund company in China acceding to the GIP. This move also demonstrates that Neuberger Berman, as an advocate for active ESG investing, has taken into account ESG issues at the corporate strategy level.

- In addition, ESG DataLab, an ESG evaluation platform developed by Morgan Stanley Huaxin Funds, a one-time joint venture that recently converted into a wholly foreign-owned mutual fund company upon CSRC approval, has used big data and AI to rate ESG performance of all A-share companies by environmental, social, and corporate governance metrics. Based on the platform, Morgan Stanley Huaxin Funds set up an ESG quant fund equipped with an ESG investment scoring feature by applying strict criteria to rule out companies with poor fundamental analysis scores and low ESG ratings, and to prioritize listed companies showing good performance on all ESG dimensions; it also adds local factors and perspectives when making ESG evaluations to improve objectivity and accuracy. With respect to post-investment management, the company has formed an ESG leadership team to formulate a set of supervisory rules on the investee companies, namely an ESG dynamic management system, to continuously follow and update ESG performance of the portfolio companies[13].

- On January 19, 2023, UBS SDIC Fund Management Co., Ltd., a PRC-based joint venture established by UBS AG and SDIC Taikang Trust Co., Ltd., was announced to have become the first PRC-based signatory to the Net Zero Asset Managers Initiative (NZAM). The move will further enhance UBS SDIC's ability to research the impact of climate and environmental factors on investment. At the product level, the company integrates ESG metrics into the valuation process of its equity products and has launched investment fund products focusing on the new energy industry[14].

- Fidelity International has extensive practical experience in ESG investing. The company adopts an ESG rating methodology that emphasizes fundamental analysis while comprehensively considering the investees' ESG information collected from their corporate disclosures and its regular meetings with the management of the investee companies. It has also formulated the Sustainable Investing Voting Principles and Guidelines, setting out basic ESG standards for investee companies. Since 2019, Fidelity International has launched the Sustainable Family fund range, among which the Focus funds actively seeks to select companies that are superior performers on sustainability issues relative to their peers, while Sustainable Thematic funds use an investment approach that contributes to addressing sustainability challenges or creates positive value-add for society and the environment. With respect to post-investment management, Fidelity International regularly communicates with investee companies and exercises its voting power in an effective manner. FIL Fund Management (China) Company Limited, as a PRC-based wholly foreign-owned mutual fund management company, will localize

[13] *How to Pinpoint Investees through the ESG Lens? Exploring the SRI Methodology of Morgan Stanley Huaxin Funds*: https://baijiahao.baidu.com/s?id=1701260456383098919&wfr=spider&for=pc.

[14] *UBS SDIC Fund Becomes the First PRC Signatory to NZAM*: https://baijiahao.baidu.com/s?id=1755437988109677180&wfr=spider&for=pc.

its global ESG experience in China and integrate this experience into its investment process[15].

2. Foreign-invested private securities investment fund managers

Foreign-invested private funds have been actively expanding into the Chinese market, driven by their expectations and confidence in its abundant investment opportunities. At present, there have been 34 foreign-invested private securities investment fund managers licensed to do business in China.

A series of foreign-invested institutions, especially these private securities investment fund managers, have started to establish more professional assessment methods and systems for the green performance of investment targets such as positive assessments, negative lists, normalized risk monitoring mechanisms, emergency response development, and other such relevant systems and procedures. The ESG investment of foreign-invested private securities institutions will also grow in lockstep with the development of the domestic ESG system in China.

3. Foreign investors participating in the Chinese market

In June 2018, A shares were officially included in the MSCI Emerging Markets Index and the MSCI ACWI Global Index, and all A-share companies included in MSCI indexes are subject to ESG ratings. The MSCI ESG Ratings, conducted once every year, range from leader (AAA, AA), average (A, BBB, BB) to laggard (B, CCC). The move to include A-share companies in the MSCI ESG Ratings provides an important reference for foreign investors participating in Chinese securities investment through various channels - including but not limited to such cross-border channels as QFI, Shanghai/Shenzhen-Hong Kong Stock Connect and Bond Connect - spurring the opening-up of A-share companies to foreign investment and positive changes from an ESG perspective.

II. ESG Localization

Overall, ESG investment in China its still at an initial stage with extensive space for development and investment opportunities. For asset managers and long-term investors participating in the Chinese market, although their overseas peers provide useful references with respect to ESG investment strategies and experience, it is still necessary to devise investment strategies that are applicable to local investment needs, assessment and rating methods, and market realities. Moreover, fund managers are advised to spend more time establishing and refining their internal processes and systems to better integrate ESG factors into investment research, post-investment management, daily risk monitoring, and other aspects.

The anti-ESG backlash

Despite its worldwide popularity in recent years, ESG remains conceptually immature, with uneven levels of development in different countries and markets. As a result, challenges and opposition to ESG arose at the end of 2021 and flourished throughout 2022, which has led to a growing polarity between ESG and anti-ESG advocates. Given that, fund managers and long-term investors are advised to consider both the positive impact of ESG and the potential perils of reckless pursuit of ESG goals in their daily operations

[15] Fidelity International released the 2022 Sustainable Development (ESG) Investment White Paper.

and investment process.

I. Core beliefs of anti-ESG advocates

Sustainable development and economic benefits have always been the main focus of corporate operations. Development pathways seeking environmental protection, balance, and inclusiveness will surely affect short-term financial returns that are more direct and visible. This is also the main concern of anti-ESG advocates, who primarily hold the following opinions against ESG[16].

- ***Difficulty in forming uniform rating standards and the lack of transparency*:** Different ESG rating agencies can hardly come up with uniform rating standards and the rating criteria, methodologies, and details of those rating agencies are only partially disclosed or wholly undisclosed due to claims of trade secrets protection, inviting doubts about impartiality of the ratings.
- ***Confusion over a company's essential responsibility*:** The concept of ESG may be a deviation from a company's primary responsibility, which is to earn as many profits and returns as possible for its shareholders. Overemphasizing ESG or CSR may hold a company "responsible for everyone, which ultimately makes it irresponsible for everyone".
- ***The paradox of short-term returns and long-term development*:** The essence of ESG is sustainable development, which, as mentioned above, will cause uncertainty to, or even sometimes compromise, a company's earnings. Thus, companies are confronted with a practical dilemma of how to balance financial income and non-financial benefits in their business endeavors.

The anti-ESG wave has also raised the attention of many economists who actively take part in public discussions on this topic. For example, The Economist recently published an article centering on anti-ESG, citing the opinion of the Nobel-prize winning economist Milton Friedman who posited that "a company's responsibility above all else was to provide returns to its shareholders". The article also argues that determining whether assets are ESG-compliant is complex and prone to bias, mismeasurement, and public-relations problems[17].

II. The anti-ESG movement and international waves

The United States has so far become the epicenter of the anti-ESG movement. At the policy level, lawmakers in conservative-leaning states have begun to introduce anti-ESG legislation, represented by the states of Florida and Texas: Florida's state governor passed a resolution to bar the state's pension fund from considering ESG factors when making investment decisions, while in Texas, some pro-ESG investment institutions are banned from entering into contracts with the state and local entities. Also, in March 2023, the Senate voted to overturn a Labor Department rule issued in November 2022 that permits fiduciary pension fund managers to consider ESG factors in their investment decisions on

[16] *What Are the "Anti-ESG" Arguments?* https://www.huxiu.com/article/779009.html.

[17] *The anti-ESG industry is taking investors for a ride*: https://taizihuang.github.io/TheEconomist/html/the-anti-esg-industry-is-taking-investors-for-a-ride.html.

the ground that considering ESG factors would undermine fund returns. On March 20, 2023, President Joe Biden used the first veto of his presidency to reject the bill and continue promoting the Labor Department's rule, allowing pension fund managers to base investment decisions on ESG factors. However, it is commonly believed in the industry that the narrow survival of the Labor Department rule may only be a prelude to the battle between the Democrats and the Republicans around ESG issues.

At the product level, the financial market has witnessed the continuous launch of anti-ESG products. At the end of 2021, BAD ETF, the first anti-ESG ETF product, was rolled out in the US, with a special focus on gambling, alcohol, and drug manufacturing enterprises; on August 9, 2022, Strive Asset Management launched DRLL, its landmark "anti-ESG fund", with a focus on energy sectors including petroleum, coal, and natural gas. On December 7, 2022, Vanguard Group Inc., the world's biggest mutual fund manager, pulled out of the Net Zero Asset Managers Initiative (NZAM), the world's largest investment-industry initiative on tackling climate change, as a concession to its anti-ESG clients[18].

From a global perspective, while the United States is dealing with the sweeping influence of the anti-ESG wave, Europe remains the major playing field for sustainable funds.

Our viewpoint

Per our observation of today's market, a large number of market participants have integrated ESG into their investment process, or at least have shown an interest in ESG, though no evidence is strong enough so far to prove that, measured by return on investment, ESG-themed products in general outperform non-ESG products on a significant basis. The ESG concerns of market participants cover not only carbon footprints, but also labor issues, effective corporate governance, balance of interests, and diversity, among others. It is a common belief in both domestic and overseas markets that multifaceted thinking will facilitate wiser decisions both at the management level and throughout the entire organization. Thus, corporates should consider as many dimensions as possible in their decision-making to achieve high-quality financial growth and acquire sustainable returns. Moreover, active ESG engagement will also benefit an enterprise in aspects such as talent strategies and social reputation. According to survey results of world-renowned corporate management consulting firms regarding ESG impact on enterprises, top employers, as measured by employee satisfaction and attractiveness to talent, have significantly higher ESG scores than their peers, suggesting that ESG performance can help companies both improve employee satisfaction and attract prospective employees[19]; on the other hand, companies failing to act on ESG issues risk damaging their reputation and credibility[20]. These findings are basically consistent with

[18] *The World's Biggest Mutual Fund Manager Exits NZAM*: https://chinese.aljazeera.net/economy/2022/12/8/%e5%85%a8%e7%90%83%e6%9c%80%e5%a4%a7%e7%9a%84%e5%85%b1%e5%90%8c%e5%9f%ba%e9%87%91%e7%ae%a1%e7%90%86%e5%85%ac%e5%8f%b8%e9%80%80%e5%87%ba%e5%87%80%e9%9b%b6%e6%8e%92%e6%94%be%e5%80%a1%e8%ae%ae.

[19] *ESG as a Workforce Strategy*: https://www.mercer.com/our-thinking/esg-as-a-workforce-strategy.html#:~:text=ESG%20performance%20will%20become%20increasingly%20important%20to%20attracting,world%E2%80%99s%20workforce%2C%20compared%20to%2052%20percent%20in%202019.

[20] *Companies failing to act on ESG issues risk losing investors, finds new PwC survey*: https://www.pwc.com/lt/en/about/press-room/pwc-global-investor-esg-survey.html.

our observations of the market.

Given the growing importance of ESG as a key consideration in investment decisions, there is a potential risk that companies may exaggerate their ESG performance and contribution through partial or fabricated ESG disclosures, namely engaging in “greenwashing”, in order to attract investors and obtain easy profits. Enterprises are advised to recognize the superior importance of ESG-compliant actions to their reputational needs and to implement ESG measures in real terms through consistent ESG disclosures, improvement of ESG management, and proactive ESG interaction with the market, so that ESG will be truly embedded in corporate operations and business activities rather than being reduced to window dressing tactics.

Given our observation of market practices and a broad range of views, we have come to believe that, contrary to the pursuit of short-term, visible benefits, ESG emphasizes a sense of responsibility for the long-term wellbeing of humanity as well as the expectations and risk control for the future. ESG is not an investment philosophy that denies other investment methods; instead, it is a series of theories and methodologies that aim to channel enterprises, business, and capital into virtuous development in the long run. ESG is a philosophy that inspires enterprises to consider what might affect their future development on multiple fronts rather than the single dimension of financial returns. As a concept in support of sustainable development, ESG has been widely acknowledged in the international community and has been used as a bridge to facilitate effective communication among corporate stakeholders.

We are of the opinion that, in the long run, ESG will exert positive influence on investment activities in the market. ESG considerations are indispensable especially for long-term investment even though they may require significant expenses in the early stages and may not generate instant, visible returns.

We will pay close attention to the development of ESG regulation and practices in the investment field and continue to contribute our observations and insights.

2. New LDT Pilot Regulations Key Takeaways

Authors: Aaron GU | Pengfei YOU | Duzhiyun ZHENG | Fengqi YU[21]

In recent years, China is continuously exploring the regulations of LDT (Laboratory Developed Tests, as defined below). With the introduction of a series of new regulations, many outstanding multinational and local companies have participated in the research of LDT. At this stage, general provisions can no longer meet the demand of the practice of LDT industry. Recently, Shenzhen, Guangzhou, Hangzhou, Beijing and Shanghai have successively introduced favorable policies to support the development of LDT. In early 2023, the National Medical Products Administration of PRC ("**NMPA**") and the National Health Commission of PRC ("**NHC**") jointly issued the *Notice of Carrying Out the Pilot Program of Development and Use of Medical Institution Developed In Vitro Diagnostic Reagents* ("**National LDT Pilot Regulations**"). In March, Shanghai MPA and Shanghai Health Commission jointly issued the *Implementation Plan for the Pilot Program of Development and Use of Medical Institution Developed In Vitro Diagnostic Reagents* ("**Shanghai LDT Pilot Regulations**"). The introduction of National LDT Pilot Regulations and Shanghai LDT Pilot Regulations marks the beginning of the implementation stage of China's regulation on the LDT industry, thereto making the regulatory methodology clearer and taking a significant step to a more comprehensive and mature regulatory system in the future. This article will introduce the key aspects of the National LDT Pilot Regulations and Shanghai LDT Pilot Regulations and make comparison on the commonalities and differences between the two regulations, for the purpose of providing reference for the industry.

Laboratory Developed Tests, or namely LDT, originates in the United States and is a product differentiated from commercialized in vitro diagnostic ("**IVD**") products with marketing approval. Some clinical laboratories choose to develop and use LDT to fill in the gaps of marketed IVD products in diagnosing certain diseases in the market. In 1988, the U.S. Congress passed the bill of Clinical Laboratory Improvement Amendments, allowing the clinical laboratories' development and use of LDT.

In China, the official definition of LDT is a testing product used exclusively within the laboratories, which shall not be sold to other laboratories or medical institutions, but the results of which can provide guidance for clinical diagnosis and treatment, according to the *Technical Guidelines for the Application of Personalized Medical Testing of Sequencing Technology (Trial)* issued by the National Health and Family Planning Commission of PRC (the predecessor of the NHC).

According to Article 10 of the original *Regulations for the Supervision and Administration of Medical Devices* issued in 2000, the medical institutions can develop medical devices according to their own clinical needs and use them in their own institutions with the guidance of licensed physicians. However, this article is deleted in the revised versions of such regulation in 2014 and 2017. To sum up, despite the LDT programs have been carried out by some medical institutions for a long period, its legal and regulatory basis is not solid.

[21] Shuwen Sun and Leyi Wang have contributions to this article.

This situation persisted until 2021, when the currently effective *Regulations for the Supervision and Administration of Medical Devices (Revised in 2021)* were stipulated. Article 53 points out that, regarding IVD reagents for which no product of the same variety has been authorized for marketing in China, a qualified medical institution may, according to its clinical needs, develop and produce them by itself and use them within its own institution under the guidance of licensed physicians, which provides an official legal basis for LDT industry at the level of administrative regulations and started a new phase of development and regulation in China's LDT industry. However, the provision is rather general, and issues such as the criteria of "no product of the same variety has been authorized for marketing in China", the scope of "qualified medical institution", the understanding of "under the guidance of licensed physicians" and the boundaries of terms "in-house developed and produced" and "within its own institution" remain unclear and have caused many controversies and confusion in the practice. Accordingly, the series of pilot regulations mentioned above provide regulatory direction and pathway for the industry. We will introduce some key aspects of National LDT Pilot Regulations and Shanghai LDT Pilot Regulations in the following paragraphs.

Overview of pilot regulations and regulatory authorities

I. Issuing authorities and hierarchy of regulations

National LDT Pilot Regulations are directly issued by two ministry-level departments, respectively the NMPA and NHC. Although the medical institutions listed in such regulations are all in Beijing, the scope of pilot program also covers Shanghai since both Shanghai MPA and Shanghai Health Commission also appear as the receiving parties of the regulation. Shanghai LDT Pilot Regulations are jointly issued by Shanghai MPA and Shanghai Health Commission and are the implementation plan effective within Shanghai based on National LDT Pilot Regulations.

II. Division of responsibilities among regulatory authorities

National LDT Regulations have made clear the regulatory duties of competent authorities:

- The national competent authorities (NMPA and NHC) are responsible for the organization and management of the pilot program, and the provincial competent authorities are responsible for the supervision at their administrative regions.
- The regulation maintains the division of regulatory responsibilities between MPA and Health Commission at all levels. MPA is responsible for supervising products, including the filing of pilot products and post-filing quality supervision. The Health Commission is responsible for supervising medical institutions, including supervision of the use of pilot products by pilot institutions.

Additionally, both National LDT Pilot Regulations and Shanghai LDT Pilot Regulations emphasize pilot medical institution's responsibilities in quality safety and clinical use safety of its own LDT products.

III. Tasks and expected results of pilot program

The pilot program emphasizes on fulfilling urgent clinical needs and protect patients' rights, as well as

fulfilling the responsibilities of medical institutions, while the purpose of pilot program in Beijing and Shanghai are to create and form reproducible administration process and specific requirements and lay the foundation of a nationwide regulation of LDT. However, the pilot program herein is carried out in a narrow scope since the pilot medical institutions only involve a small number of hospitals but no independent clinical laboratories (ICLs) in both National LDT Pilot Regulations and Shanghai LDT Pilot Regulations. Shanghai Health Commission once provided a general direction for LDT pilot program in the *Notice of Carrying Out the Pilot Program of High-quality Development of Shanghai Public Hospitals* issued in 2022 that where conditions permit, hospitals may carry out pilot program of LDT in accordance with relevant regulations, and dozens of hospitals were enumerated as pilot institutions in the attachment of the notice. However, the Shanghai LDT Pilot Regulations specify a small-scale implementation, listing only four hospitals as pilot institutions.

Although ICLs are not included in the scope of pilot institutions in the pilot program released this time, we understand that, according to Article 53 of the *Regulations for the Supervision and Administration of Medical Devices*, if an ICL obtains a "Medical Institution Practice License", it can still explore ways to carry out LDT service in compliance as a legitimate medical institution. We also expect more hospitals and ICLs to be included in the LDT pilot scope in the future to meet the actual needs of clinical testing.

In addition, it is worth mentioning that, given the increasing attention to the real-world data (RWD/RWE), both the National LDT Pilot Regulations and the Shanghai LDT Pilot Regulations mention the exploration of the path of applying the clinical data generated during LDT use to IVD registration, forming a clear conversion pathway from LDT to IVD. This shows that the innovative development model of LDT to IVD conversion has been explicitly supported and encouraged. I n practice, one of the main reasons for the development of LDT service is to offset for the long registration period of IVD products and to meet clinical needs as a beneficial supplement to traditional IVD products. As commercial products with market approval and large-scale production and use, IVD products are more reliable in safety and should remain the mainstream of the testing service industry. Therefore, encouraging the innovative development model of LDT to IVD conversion essentially utilizes LDT as a pre-transition for IVD, which is conducive to the rational and orderly development of related products.

Moreover, the Shanghai LDT Pilot Regulations also emphasize the priority of meeting the clinical needs of pilot medical institutions in the diagnosis and treatment of rare diseases and birth defect diagnosis, which clarifies the focus and encouragement direction of LDT industry.

The scope of pilot hospitals and varieties

I. Scope and requirements of pilot hospitals

The National LDT Pilot Regulations list a total of six hospitals as pilot medical institutions, including Peking Union Medical College Hospital, Beijing Hospital, China-Japan Friendship Hospital, Cancer Hospital Chinese Academy of Medical Sciences, Fuwai Hospital Chinese Academy of Medical Sciences, and Peking University First Hospital. The Shanghai LDT Pilot Regulations list a total of four hospitals, including Fudan University Shanghai Cancer Center, Shanghai Children's Medical

Center affiliated to Shanghai Jiao Tong University School of Medicine, Zhongshan Hospital affiliated to Fudan University, and Ruijin Hospital affiliated to Shanghai Jiao Tong University School of Medicine.

Both the National LDT Pilot Regulations and the Shanghai LDT Pilot Regulations have requirements for the personnel and management system of the pilot hospitals. The key points can be summarized as follows:

1. In terms of personnel:

- The principal responsible person of the pilot hospital is fully responsible for the R&D, production, and use of in-house made reagents;
- Staffing with the project leader and quality leader for in-house made reagents. Both must be full-time staff of the institution, and the Shanghai LDT Pilot Regulations further clarify that the two positions must not be held by the same person;
- The project leader is responsible for the operation and management of the in-house made reagent project, including project establishment, research, verification, production, and use; and
- The quality leader is responsible for the establishment and operation of the quality management system for in-house made reagents, product release, and other quality management tasks.

2. In terms of institutional management systems:

- Set up necessary internal management institutions with the corresponding personnel, site, conditions, and capabilities;
- Establish a corresponding quality management system and internal review system;
- Set up corresponding academic review boards and ethics committees;
- Establish a management system to prevent the risk of in-house made reagent use, including adverse event monitoring system;
- Establish an in-house made reagent information management system to conduct full traceability and dynamic management of the R&D, production, and use of in-house made reagents throughout the process; and
- Have corresponding diagnostic and therapeutic subjects and practicing physicians.

II. Academic review in addition to ethics review

It is worth noting that in the pilot program, in addition to requiring pilot medical institutions to establish ethics committees for ethics review in accordance with the relevant requirements of the *Measures for the Ethics Review of Biomedical Research Involving Human Subjects, Measures for the Ethics Review of Life Science and Medical* Research *Involving Human Subjects* and *Good Clinical Practice for Medical Device Trials*, it also requires medical institutions to establish an academic review system to review the necessity, scientific soundness, and safety of LDT projects. The Shanghai LDT Pilot Regulations specifically state that the personnel composition of the academic review institution should

be adapted to the LDT R&D and production, and the academic committee should consist of personnel with deputy senior professional or above in various fields such as clinical, testing, and management. The content of the academic review to be conducted includes but is not limited to:

- Whether it is scientific and feasible, and the clinical application is irreplaceable;
- Whether it can ensure safety, effectiveness, and quality control;
- Whether it has the conditions and capabilities to carry out in-house made reagents;
- Whether risk prevention and control measures have been established for potential risks;
- Whether quality control measures have been established for the use process; and
- Whether the production process can meet the relevant requirements of the quality management system.

From the perspective of personnel composition, the academic review committee should be composed of personnel with professional and technical tittle of vice-senior level (副高级) or above in different specialties such as clinical, laboratory, and management, while the ethics committee, according to the provisions of the *Measures for Ethics Review of Life Sciences and Medical Research Involving Humans*, should be composed of experts in the fields of life sciences, medicine, bioethics, and law, and experts from outside the institution. Therefore, there are certain differences in personnel composition requirements between the two committees, and we understand that if a single committee is to undertake the responsibilities of both the academic review and the ethics committee, it must have the personnel who to meet the corresponding requirements of each.

III. Scope of pilot varieties

According to Article 53 of the *Regulations for the Supervision and Administration of Medical Devices*, LDT products should be IVD reagents for which there are “no products of the same variety has been authorized for marketing in China”. However, the regulations do not provide specific criteria and subject for determination. The National LDT Pilot Regulations and Shanghai LDT Pilot Regulations clarify the criteria and subject for determining whether there are “no products of the same variety has been authorized for marketing in China”, stipulate that the scope of pilot varieties shall be regulated through guidance catalogs, and supplement quality management requirements for the products of pilot varieties.

- Criteria for Variety Determination: whether there are substantial differences in technical principles, intended uses, or fundamental improvements in clinical performance of the product, and whether the product exhibits significant differences or create new values in clinical diagnostic application;
- Authority for Determination: NMPA, in conjunction with the NHC, will organize expert discussions to make decisions;
- Guidance Catalog: pilot medical institutions shall submit materials for recommended pilot varieties through provincial MPA, and the NMPA, in conjunction with the NHC, will organize expert validation and form a pilot variety guidance catalog to regulate LDT pilot work;

- Supplementary Quality Requirements: the technical maturity and clinical significance of the relevant products of pilot varieties shall be clear, and there are clinical guidelines recommended by domestic or foreign clinical treatment guidelines or clinical research indicating clinical application conditions.

Additionally, compared to the National LDT Pilot Regulations, the Shanghai LDT Pilot Regulations provide further clarification on the requirements for submission materials for pilot varieties to MPA, making it highly practical.

Requirements for the use of LDT products

The pilot policy stipulates that specific reagents developed and used by medical institutions shall be subject to filing administration and sorts out detailed regulatory rules with respect to R&D, production, and use. When using LDT products, pilot medical institutions are required to strictly adhere to these rules, while non-pilot medical institutions can also take note of the relevant regulatory requirements and implement them as appropriate.

I. Filing administration of LDT products

In addition to pilot varieties regulated by guidance catalogs, the pilot policy further stipulates that medical institutions should apply for filing procedures to the provincial MPA before developing and using specific LDT products. The policy further specifies relevant regulatory requirements, including the requirement of filing materials, procedures, and the requirements and procedures for amending or canceling filings as needed.

As aforementioned, the filing of LDT products is primarily supervised by the provincial MPA, but the provincial Health Commission also serves as a crucial regulatory authority for LDT. According to the pilot policy, the provincial MPA is required to promptly submit filling information to the NMPA and notify the Health Commission of the same level. Furthermore, the Shanghai LDT Pilot Regulations stipulate that although pilot products shall be filed by the provincial MPA, the MPA shall collaborate with the same-level Health Commission to conduct assessments prior to filing. It's worth noting that the provincial MPA and the provincial Health Commission both retain important supervisory responsibilities during the post-filing inspections of pilot products. Both the National LDT Pilot Regulations and the Shanghai LDT Pilot Regulations specify the inspection contents, timing, and mutual notification requirements for the two regulatory authorities regarding post-filing inspections of LDT products within their administrative regions.

1. Inspection Items and timeline of post-filing inspections by MPA

- Inspection Items: whether filing materials meets the regulatory requirements, whether the developed product is consistent with filing information, and whether develop and production process complies with GMP;

- Inspection Timeline: on-site inspection towards filed products within 3 months after filing, and at least one supervision inspection of the pilot medical institution at the 6th and 12th months, respectively, after the pilot program carried out (or after filing as stipulated in the Shanghai LDT

Pilot Regulations).

2. Inspection items and timeline of post-filing inspections by health commission

- Inspection Content: whether the medical institution meets the requirements of the qualification conditions and whether the products are used in accordance with the regulatory requirements;
- Inspection Timeline: inspection of medical institutions at the 6th and 12th months, respectively, after the pilot program carried out (or after filing as stipulated in the Shanghai LDT Pilot Regulations).

II. Production requirements for LDT product

According to the pilot policy, when medical institutions produce their own LDT products, they should comply with the requirements of the Good Manufacturing Practice (GMP) for medical devices, ensuring that the quality management system is effectively implemented and that the products are produced strictly in accordance with the filed technical requirements to ensure that the in-house made reagents meet such technical requirements. We understand that the requirements of the pilot policy are relatively strict, and in practice, medical institutions may find it difficult to comply with the GMP for medical devices. Therefore, it is highly likely that they will need to outsourced production.

The pilot policy innovatively provides for a system of outsourced production of LDT products. Article 53 of the *Regulations for the Supervision and Administration of Medical Devices* stipulates that LDT products shall be "in-house developed and produced" by medical institutions. On the basis of the aforementioned regulations, both the National and Shanghai LDT Pilot Policies have innovatively established that medical institutions, in addition to in-house made LDT products, may also commission qualified medical device manufacturers to produce them. Compared to the National LDT Pilot Regulations, the Shanghai LDT Pilot Regulations take a step further in exploring the outsourced production system. While the National policy stipulates that pilot hospitals shall develop and produce their own reagents, and only outsource the production if they lack the capacity to do so, the Shanghai policy clarifies that pilot hospitals only need to have the ability to develop reagents, and can freely commission qualified medical device manufacturers to produce LDT products. Regarding the commissioning of production, the following points should be noted:

1. Qualification requirements for outsourced production companies

- possess a Medical Device Manufacturing License, with the scope of production including Class II or Class III IVD reagents;
- possess relevant production experience of similar IVD reagents.

2. Outsourced contract and quality agreement arrangements

- medical institutions shall sign commissioning contracts and quality agreement with outsourced production companies to clearly define the rights and obligations of both parties with respect to the protection of quality and safety of in-house made reagents.

3. Responsibilities and obligations of medical institutions

- supervise the production process of the outsourced production companies;
- be responsible for ensuring the quality of reagents produced by the outsourced production companies.

4. Responsibility and obligations of outsourcing production companies

- produce the reagents in accordance with relevant laws and regulations, GMP for medical device, mandatory standards, product technical requirements, outsourced contracts and quality agreements;
- be responsible for the production of the reagents;
- be subject to supervision by the commissioning medical institution.

The pilot policy also specifies the release requirements for clinical-use LDT products, stating that medical institutions are responsible for releasing finished products and shall establish product release and use procedures, the criteria and conditions of which being made clear. LDT products can only be used in clinical setting after the authorized release personnel have been audited and confirmed in accordance with the requirements of the quality management system.

III. Requirements for the use of LDT products

According to the National LDT Pilot Regulations, the specific use requirements of LDT products include under the guidance of licensed physicians, registering or filling supporting medical device in compliance, establishing sound patient rights protection, risk control and adverse event management systems, and fulfilling regular reporting obligations on product use to the provincial MPA. The Shanghai LDT Pilot Regulations are more comprehensive and strict than the National LDT Pilot Regulations, which supplement regulatory requirements and provides more detailed provisions. Specifically, the regulations supplement the requirement for medical institutions to recall products in the adverse events when necessary and establish record system for developing, producing, and using reagents, maintaining relevant documentation for a minimum of three years.

Notably, according to the Shanghai LDT Pilot Regulations, the scope of “its own institution” (i.e., the medical institution producing respective reagents) does not include medical institution consortium or other medical institutions in the group. In-house made reagents should only be used within “its own institution” and clearly identified on the packaging label as such. Article 53 of the *Regulations for the Supervision and Administration of Medical Devices* stipulates that LDT products can only be used within “its own institution” without providing clear clarification on the term’s meaning and scope, which has attracted widespread attention from the industry.

In the current LDT industry, different business models exist, such as cooperations between R&D entities and medical institutions within a medical consortium, medical institutions partnering with ICLs on LDT service, and medical institutions establishing in-house laboratories in collaboration with other enterprises to conduct LDT service. The compliance of these business models largely depends on

regulatory understanding of the meaning and scope of "its own institution," which is significantly important for the development of LDT service. It's clear that the Shanghai LDT Pilot Regulations have quite stringent regulatory requirements, restricting the use of LDT products to within the medical institution itself. We understand that in the early stages of the pilot program, regulatory authorities may tend to adopt a more cautious and conservative regulatory methodology. As the regulatory system evolves and matures, corresponding regulations may become more flexible and adaptable, and we'll keep a close eye on it.

Conclusion

Given the vigorous demand for LDT in clinical practice, China's exploration of LDT regulatory policies has entered a new stage in recent years. The pilot policies implemented in Beijing and Shanghai undoubtedly provide an important blueprint for the development of a mature LDT regulatory system and pave the way for future exploration. Although the current LDT pilot policies are rather cautious, we understand that it is in line with China's experience in regulating LDTs at this stage. These policies will help to explore and develop sound regulatory frameworks for LDT under controllable risks. We believe that with the accumulation of positive regulatory experience, future policies will become more flexible and open, to meet the demands from different regions and enterprises.

Important Announcement

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

If you have any questions regarding this publication, please contact:

Beijing	**Wenyu JIN**	**Attorney-at-law**
	Tel:	+86 10 8525 5557
	Email:	wenyu.jin@hankunlaw.com
Shanghai	**Yinshi CAO**	**Attorney-at-law**
	Tel:	+86 21 6080 0980
	Email:	yinshi.cao@hankunlaw.com
Shenzhen	**Jason WANG**	**Attorney-at-law**
	Tel:	+86 755 3680 6518
	Email:	jason.wang@hankunlaw.com
Hong Kong	**Dafei CHEN**	**Attorney-at-law**
	Tel:	+852 2820 5616
	Email:	dafei.chen@hankunlaw.com
Haikou	**Jun ZHU**	**Attorney-at-law**
	Tel:	+86 898 3665 5000
	Email:	jun.zhu@hankunlaw.com
Wuhan	**Jiao MA**	**Attorney-at-law**
	Tel:	+86 27 5937 6200
	Email:	jiao.ma@hankunlaw.com
Singapore	**Lan YU**	**Attorney-at-law**
	Tel:	+65 9839 8208
	Email:	lan.yu@hankunlaw.com