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New Medical Reform in China: Pharma Companies' Tax Challenges, Opportunities and Responses

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Preface

In recent years, the Chinese government has introduced a series of laws and regulations to deepen reform of its healthcare and medical system (new medical reform), with the primary aim of lowering drug prices and improving people's welfare while encouraging innovation and drug development. The key areas of new medical reform include Volume-based Procurement (VBP), the dynamic adjustment mechanism of the medical insurance catalogue (Dynamic Catalogue Adjustment), the Two-Invoice System and the Marketing Authorization Holder (MAH) system.

New medical reform will further promote innovation and development in China's pharmaceutical industry, and will accelerate industry reorganization. Pharmaceutical enterprises need to adapt to the general trends in new medical reform to assess their business models and future development. These considerations are bound to affect their operations, so pharmaceutical enterprises need to promptly adjust their business models and supply chain management to establish solid foundations for the sustainable development of their businesses and capture expected huge growth in the Chinese market. Tax compliance and planning are important considerations for pharmaceutical companies during business model and supply chain adjustments. Reasonable tax planning and risk management not only reduce and optimize overall tax burden, and improve investor return, but also effectively manage tax risks.

Starting from the key policies in new medical reform, this article elaborates on the tax challenges, opportunities and response strategies for pharmaceutical enterprises. The key views are:

- Cost pressures from drug price cuts will force intra-group functional realignments, while group entity functional and risk re-positioning and appropriate transfer pricing policy approaches will create opportunities to improve tax efficiency
- Sales and distribution channel restructuring under the Two-invoice System highlight the importance of tax compliance and risk management
- Innovation and R&D are becoming the core competitiveness of pharmaceutical companies, and tax and transfer pricing planning around R&D functions and IP ownership will be the "core of the core" in improving tax efficiency and risk management
- Specialization is becoming an industry trend, alongside the widely used CMO/CRO/CDMO models, making tax model choice important in reducing overall tax burden
- Increased M&A and restructuring opportunities expand the need for prior tax assessment and the establishment of enhanced tax models post M&A or restructuring
- Corresponding to China market share capture and supply chain realignment strategies, multinational pharmaceutical companies should make full use of preferential local industry policies and construct tax optimized trade and supply chain models

Key policies in new medical reform

The main purpose of new medical reform is to reduce prices of medicines and healthcare, while encouraging innovation and invigorating market players. To this end, the Chinese government has introduced key policies including VBP, Dynamic Catalogue Adjustment and the Two-Invoice System, which guide enterprises to reduce drug prices. In the meantime, the Drug Administration Law was amended to stimulate drug research and development (R&D) and increase industry vitality by unbundling the value chain of drug R&D, production and sales through the implementation of the MAH system.

Volume-based Procurement, Dynamic Catalogue Adjustment and the Two-Invoice System

- **Volume-based Procurement**
  Government authorities organize bids for centralized procurement of drugs, and centrally purchase a guaranteed volume of drugs from bid-winning manufacturers. Bidding is open to drugs that have passed evaluations for consistent quality, efficacy and safety. On 10 December 2019, the National Healthcare Security Administration issued the *Opinions on Effective Management of Current Drug Price Administration,* emphasizing deeper reform of the centralized volume-based procurement system, and espousing the principle of "procuring based on volume, linking price with volume, and integrating bidding and purchasing", to return drug prices back to a reasonable level.

- **Dynamic Catalogue Adjustment**
  In February 2020, the State Council and National Healthcare Security Administration promulgated *The Opinions on Deepening Reform of the Healthcare Security System,* which further clarified the mechanism for improving dynamic adjustment of the medical insurance catalogue for drugs. This ensures there is a dynamic "in and out" mechanism for drugs to enter or exit the catalogue. In addition to regular medical insurance catalogue adjustments, China also includes innovative drugs with high clinical value in the scope of medical insurance payments through negotiation with enterprises (the Negotiation Catalogue). The Negotiation Catalogue takes advantage of the scope of medical insurance payments and the size of national procurement to negotiate lower prices with enterprises on expensive, new and innovative drugs that are needed and have no substitutes.

- **Two-invoice System**
  The Two-invoice System requires that pharmaceutical producers issue no more than two VAT invoices for a drug to end-customers. The purpose is to reduce distribution layers and thereby depress drug costs and prices. On December 26 2016, the Medical Reform Office of the State Council and another seven departments jointly issued *The Implementing Opinions on Managing the Two-Invoicing System for Drug Procurement among Public Medical Institutions (for Trial Implementation)* (issued by the State Council Healthcare Reform Office[2016] No.4), which introduced the first national Two-invoice System regulation. Since then, the Two-invoice System, which started in pilot provinces, has been rolled out nation-wide. On one hand, the Two-invoice System is meant to strengthen supervision of drug quality and safety by increasing traceability. On the other hand, it can also improve distribution efficiency and reduce prices by removing unreasonable distribution layers.

The aim of VBP, Dynamic Catalogue Adjustment, and the Two-Invoice System is to increase competition and reduce distribution layers to cut drug prices. These policies have a profound impact on pharmaceutical companies. Drug price reductions resulting from direct VBP and Dynamic Catalogue Adjustment will motivate enterprises to control internal costs and reorganize their businesses. The Two-Invoice System will also pressure pharmaceutical companies to adjust their sales strategies and reshape sales channels, and could prompt a surge in compliance risks.

The new drug administration law and MAH system

On 26 August 2019, the Standing Committee of the Chinese Congress voted to adopt the amended Drug Administration Law of the People's Republic of China (new Drug Administration Law), which was officially implemented on 1 December 2019. On 30 March 2020, the State Administration for Market Regulation officially announced the 2020 Administrative Measures for Drug Registration (New Administrative Registration Measures) which will come into force on 1 July 2020. The New Administrative Registration Measures is an important support policy for implementation of the New Drug Administration Law.

The key changes in the New Drug Administration Law and the New Administrative Registration Measures mainly concern the drug MAH system and optimization of the review and approval process for new drug registrations.

- **The MAH System**

  Under the MAH system, pharmaceutical R&D institutions, researchers and pharmaceutical production enterprises can apply to become drug market authorization holders. Market authorization holders can engage other qualified enterprises to produce and/or sell products approved under the authorization, or transfer the authorization. The market authorization holder bears primary responsibility for drug quality throughout its life cycle.

  The MAH system ended the previous "R&D, production and sales" binding system. Previously, China's drug registration system used a bundled "marketing license" and "production license" mechanism, meaning a drug marketing license (with drug approval number) was issued only to enterprises with a drug production license. Drug research and development institutions and researchers were not qualified to independently obtain drug marketing licenses. Under the MAH system, MAHs can outsource production, sales, or even transfer their market authorization of approved drugs, to other qualified enterprises.

The Drug Administration Law also allows a MAH to be an overseas company. In this case, the overseas MAH shall designate a Chinese company to fulfill the obligations of the MAH, and it shall jointly bear the responsibility and liabilities of the MAH.

- **The optimization of new drug review and approval**
  The new Administrative Registration Measures made major changes to optimize the approval process and the drug registration management system to encourage drug innovation, including: optimizing the review and approval process, setting up priority review and approval for drugs with clinical value or urgent need, drugs for children, and drugs for rare diseases. They also include measures to speed up the approval of clinical trial applications. Under the new measures, the drug regulatory department under the State Council shall decide within 60 working days from the date of acceptance of an application for clinical trial whether to agree and notify the applicant. Where there is no rejection, it can be deemed a green light for agreeing a clinical trial's application.

The new Drug Administration Law and Administrative Registration Measures are based on experiences derived from the reform of China's drug examination and approval system in recent years. Key policies under the MAH system break the previous "research, production and selling" binding system, allowing drug MAHs to outsource production and sales, or transfer market authorization. These two key policies will be a boon for specialization and innovation in the industry, and increase its vitality.

Pharmaceutical enterprises' tax challenges, opportunities and responses amid medical reform

The impact of new medical reform on pharmaceutical companies is profound. Enterprises will need to comply with new regulatory requirements while grasping industry and market trends to be able to grow amid intensifying market competition. For many pharmaceutical companies, it is imperative to look at current business models to assess the impact of new medical reform and make prompt adjustments to ensure future growth. With business model restructuring, there is a need for corresponding tax model restructuring to manage tax risks and improve tax efficiency. Below are our observations of the tax challenges and opportunities associated with new medical reform, and our recommended strategic responses for pharmaceutical companies.

Cost pressures from drug price cuts force intra-group functional realignment, while group entity functional and risk re-positioning and appropriate transfer pricing policy provide opportunities for group-wide tax efficiency improvements

VBP and Dynamic Catalogue Adjustment are prompting sharp declines in drug prices. This has in turn been squeezing profit margins and putting considerable cost-cutting pressure on impacted enterprises. To reduce costs and enhance competitiveness, enterprises need to deploy integrated use of resources to maximize synergies, which often involves realigning group entities' roles and functions.

From a tax perspective, group functional realignment requires a group tax model that matches the new business model to manage potential tax risks. Meanwhile, an effective tax planning strategy alongside a business realignment plan will boost overall tax efficiency and enhance investment returns.

- Plan and re-position the functions of group entities (e.g. research and development, procurement, production, marketing and distribution) and arrange appropriate transfer pricing (TP) policies matching the group value chain in China or at a global level to potentially reduce overall group tax burden while maximizing business efficiency;
- Balancing the profit and loss status of entities within the group through reasonable TP arrangements to ensure effective loss usage;
- When adjusting the roles and functions of entities within the group and arranging reasonable TP policies, it is necessary to comply with the arm's length principle and respective TP rules while taking into account practices in each country or region to manage and control related tax risks.

Sales and distribution channel restructuring under Two-invoice System highlights the importance of tax compliance and risk management

Pharmaceutical companies used to sell drugs to end customers (e.g. hospitals and retailers) through multi-layer distributors. Under the Two-invoice System, manufacturers can only issue two VAT invoices to end customers, typically one for sales from manufacturers to distributors, and another for sales from distributors to end customers. Pharmaceutical companies need to re-adjust their sales strategies and channels, undertaking more direct management to integrate and manage distributors or service providers. This will bring additional tax compliance risk and risk management requirements.

From a tax perspective, the Two-invoice System highlights the importance of tax compliance and risk control for pharmaceutical companies:

- Sales and distribution channel reorganization are likely to increase pharmaceutical companies' direct sales expenses. Companies should pay more attention to the appropriate classification and tax deductibility of expenses to reduce the risk of deductions before tax and penalties being disallowed;
- Additional fees and expenses paid to outside service providers can increase companies' compliance management burden in respect of maintaining good tax compliance systems and valid tax payment records and documentation. Valid payment records and documentation are important for claiming corporate tax deductions and VAT credits. Appropriate use of technology and tax digitalization tools can improve compliance and risk management efficiency.

The Two-invoice System increases the tax compliance risk of pharmaceutical companies, and their potential tax costs. In conjunction with streamlining their sales and distribution structures, pharmaceutical companies should also assess their tax compliance and management strategies, processes and systems to ensure meticulous compliance risk management with robust documentation. Meanwhile, companies should consider appropriately using technology and tax digitization tools to increase compliance and risk management efficiency.

Innovation and R&D becoming the core competitiveness of pharmaceutical companies, and related tax planning for R&D functions and IP is becoming the "core of the core" in tax efficiency improvement and risk management

VBP and Dynamic Catalogue Adjustment could lead to fierce price competition in genetic drugs, motivating pharmaceutical companies to conduct new drug R&D. Meanwhile, the MAH system, optimization of the review and approval process for new drugs, and faster clinical trial approvals, should facilitate and encourage new drug R&D.

Pharmaceutical companies are set to increase their R&D efforts and investment to compete. New biotech R&D companies will emerge, either aiming to transfer their R&D results to other industry players for a return, or own MAH and potentially participate directly in drug production and commercialization through production or outsourcing.

From a tax perspective, pharmaceutical and biotech enterprises' increased investment in R&D means they should consider how and to what extent R&D and intangible property (IP) ownership arrangements can improve tax efficiency. Careful consideration could be given to:

- Planning the appropriate R&D business model, and arranging R&D and IP ownership related transfer pricing policies, to improve tax efficiency and reduce the risk of unnecessary double taxation;
- Maximizing use of applicable national tax preferential treatments and regional financial support policies such as high and new technology enterprise (HNTE), R&D expense super deductions, technologically advanced service enterprise (TASE), western development tax incentives and special area tax incentives (e.g. the Greater Bay Area and Free Trade Zones);
- Selecting and arranging appropriate incentive schemes for core R&D personnel (e.g. planning and building employees' shareholding platforms) who are often the senior management of a company and even the founders at new biotech companies. This can facilitate a win-win situation of reduced corporate tax and employee personal tax burdens.

Specialization becoming an industry trend in conjunction with widely used CMO/CRO/CDMO models, making tax model choice important in reducing overall tax burden

The MAH mechanism breaks the traditional binding of "development, manufacture and sales", and allows MAHs to designate other parties for production, R&D and sales. This is expected to proliferate contract manufacturing organizations (CMOs), contract research organizations (CROs), and contract development and manufacturing organizations (CDMOs) in China.

From a tax perspective, companies with group supply chains involving a CMO/CRO/CDMO should consider:

- Various tax preferential treatments and regional industry incentives. Some jurisdictions have financial support policies for certain types of pharmaceutical companies;
- The tax implications of various business models, for better tax risk management and efficiency. For example, some business models have different implications for HNTE and super-deduction qualifications. In addition, value chain allocation and corresponding transfer pricing policies should be considered to improve tax efficiency and risk management.

Increased M&A and restructuring expand the need for prior tax assessments and subsequent establishment of enhanced tax models

New medical reform is expected to result in more M&A activity, with biotech enterprises possessing innovative drugs becoming hot targets for investment institutions and capital markets.

From a tax perspective, enterprises undergoing M&A and restructuring can encounter various issues such as the qualification of special reorganization tax treatment for tax deferral purposes, the deemed direct transfer of a Chinese company's equity resulting in potentially substantial Chinese tax obligations, and potential withholding tax and turnover tax implications and optimization. Companies need to assess the potential tax implications for informed decision-making in M&A and reorganization activities. It is also important to establish an enhanced group tax model during post-M&A integration and restructuring.

Corresponding to market share capture and supply chain realignment strategies, multinational pharmaceutical companies should make full use of preferential local industry policies and build up tax optimized trade and supply chain models

Multinational pharmaceutical companies will be hit by price pressure from new medical reform in the short term, but also have opportunities to introduce new products to capture the huge and dynamic Chinese market. On one hand, they can consider reorganizing their existing businesses in response to the short-term blow from new medical reform and improve efficiency (e.g. by separating and having more centralized business strategies and management of generic and innovative drugs). On the other hand, they can speed up the introduction of new drugs to the China market to capture market share. The MAH system allows overseas enterprises to be MAHs and entrust production and sales to domestic companies. This provides opportunities for MNCs to reorganize their global and China supply chains while introducing new products to the China market. MNCs can accelerate localization of upstream drug manufacturing in China to reduce costs and increase competitiveness.

Pharmaceutical MNCs in China should revisit their tax models and reconfigure tax optimization mechanisms to factor in direct and indirect tax or customs duty considerations arising from new product introductions and supply chain realignment. With the Chinese government having identified biomedicine as a strategic emerging industry, many local governments have elevated it to the heights of a new engine of regional economic development. To this end, some provinces and cities have set up special biopharmaceutical industrial parks to attract the world's top biopharmaceutical enterprises with preferential industry policies and fiscal policies. Multinational pharmaceutical companies should make full use of these local policies in their China business expansions and new product introductions, as well as supply chain realignment.

China's new medical reform is a challenge but also an opportunity for pharmaceutical companies from a business and tax perspective. Careful tax assessment and planning during business model adjustment under new medical reform is an integral part of overall business and tax efficiency improvements for pharmaceutical companies. In particular, the cost and price pressures caused by VBP and Dynamic Catalogue Adjustment should prompt companies to adjust the positioning of intra-group entities, within which creating an appropriate transfer pricing policy is key to improving group tax efficiency. Meanwhile, sales and distribution channel restructuring, which is often a direct result of the Two-invoice System, highlights the importance of tax compliance and documentation management to ameliorate risks. With the MAH system and encouragement for innovation, R&D is becoming companies' core competitiveness, and related tax and transfer pricing planning around R&D and IP ownership is becoming the "core of the core" for overall tax efficiency improvements and risk management.

New medical reform is also bringing about increased industry specialization and M&A activity, which again highlights the importance of prior tax assessments for informed decision making and business and tax model selection. Multinational pharmaceutical companies need to revisit their China business and supply chain plans to mitigate the short term price and cost pressure from new medical reform and introduce new products to capture market growth, supported by full use of local preferential policies and the creation of tax-optimized trade and supply chain models.

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