



Challenges of the 'two invoices' system for China's pharmaceutical industry

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Regulations discussed in this issue:

Opinion on the Implementation of the 'Two Invoices' System in the Procurement of Pharmaceutical Products by Public Medical Institutions (trial) (Guoyigaibanfa [2016] No. 4, hereinafter referred to as "Circular 4")

Background

On 26 December 2016, the State Council Healthcare Reform Committee, National Health and Family Planning Commission, National Development and Reform Commission, Ministry of Industry and Information Technology, Ministry of Commerce, State Administration of Taxation and State Administration of Traditional Chinese Medicine jointly released *Opinion on the Implementation of the 'Two Invoices' System in the Procurement of Pharmaceutical Products by Public Medical Institutions (trial)* (Guoyigaibanfa [2016] No. 4, hereinafter referred to as "Circular 4"), which was officially released on 9 January 2017.

The 'two invoices' system stems from the *Announcement on Regulating Pharmaceutical Procurement* ("the Announcement"), which was jointly released by the National Health and Family Planning Commission and other relevant authorities. The Announcement aimed to streamline the pharmaceutical procurement process, stating that "the manufacturers of pharmaceutical products shall directly bid for the procurement instead of the distributors. The manufacturer shall perform direct delivery or commission a qualified distributor with modern logistics capacity to deliver the pharmaceutical products. In principle, along the chain of pharmaceutical products delivery, the commissioned distribution shall only be carried out once. In cases where the commissioned distributor is not able to perform the delivery directly, with the approval of the pharmaceutical procurement administration on a provincial level, a third party is allowed to be engaged to make the delivery."

The streamlined initiative was first implemented as part of the Sanming Healthcare Reform, which took place in the city of Sanming, Fujian Province. Sanming Healthcare Reform introduced a four-in-one reform model – governmental reform, drug procurement reform, medical insurance reform and medical service reform. The reform blazed a trail and is inspiring future reform on a national scale.¹

Inspired by the Sanming reform, a number of provinces within and outside the scope of the pilot healthcare reform have also announced similar policies encouraging the 'two invoices' system since June 2016, setting the tone for the reforms going forward. By the end of January 2017, a total of 27 provinces, provincial-level municipalities and autonomous regions (excluding Hong Kong SAR, Macau and Taiwan) have committed to rolling out the 'two invoices' system to some extent. Of those, 17 provinces (including Fujian, Anhui, Shanxi and Hunan provinces) have already rolled out or will roll out the 'two invoices' system soon. The other 10 provinces (including Gansu, Liaoning and Jiangxi) will encourage the roll-out of the 'two invoices' system. We have prepared a summary of the regional policies up to the issuance of this paper, which is attached as Appendix 1.

The purpose of this paper is to highlight and analyse the salient points of Circular 4, and the implications for the pharmaceutical industry. We also explore and set out our thoughts on the tax implications of the 'two invoices' system for pharmaceutical companies in China.

1. For detailed information regarding Sanming Healthcare Reform, please refer to KPMG's research report – 'Sanming: The real story of grass-roots healthcare transformation in China', November 2016, <https://home.kpmg.com/cn/en/home/insights/2016/11/healthcare-reform-report.html>

Highlights of Circular 4

The recently released Circular 4 is a detailed explanation of the 'two invoices' system at a national level, and mainly addresses the following questions.

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What is the 'two invoices' system?

The 'two invoices' system refers to the mechanism where only up to two invoices are issued along the chain of pharmaceutical product procurement, with one issued by the pharmaceutical manufacturer and the other issued by the distributor to the medical service providers. Compared with the pre-reform procurement model, the 'two invoices' system eliminates multiple layers of distributors, and significantly streamlines the procurement process.

In addition to the pharmaceutical manufacturer, Circular 4 also introduces the types of enterprises which can be regarded as deemed pharmaceutical manufacturers:

- Commercial enterprises which are fully owned or controlled by a pharmaceutical manufacturer, or a pharmaceutical group with an integrated research-manufacture-

trade function (“科工贸一体化的集团型企业”); they should be engaged in the distribution of pharmaceutical products produced by their own company/group only.

- The authorised general agent (the only one for China) of imported pharmaceutical products.
- For the Pharmaceutical Trading/Distribution Group (“药品流通集团型企业”), intra-group transfers of pharmaceutical products (e.g. from the parent to its subsidiary or between the affiliates within the group) will not be regarded as the issuance of one invoice as defined in the 'two invoices' system. The intra-group transfer privilege can only be invoked once along the line of distribution within the group.



What is the purpose of the 'two invoices' system?

Before the reform, the multiple layers of distributors and medical representatives along the supply chain, the complex distribution network, and the lack of transparency inflated the price of pharmaceutical products to some extent. The 'two invoices' system aims to

regulate and streamline the pharmaceutical products distribution, creating a healthy distribution environment where the price of pharmaceutical products is reasonable and affordable for the public.



What are the scope, timeline and invoicing requirements?

Scope and timeline

The 'two invoices' system will be phased in among publicly owned medical institutions, and other medical institutions are encouraged to adopt the system in their procurement process. Provinces and municipal cities covered by the pilot healthcare reform scheme shall take the lead in implementing the system, and the implementation shall be encouraged in other regions. A nationwide implementation is expected by 2018.

Invoicing requirements

The 'two invoices' system provides more detailed invoice and documentation compliance requirements for pharmaceutical manufacturers and distributors.

For sales from pharmaceutical manufacturers:

- A VAT special invoice or general invoice

shall be issued and the 'Accompanying Bill' (随货同行单) shall be attached.

- The buyer and seller as shown on the invoice shall be consistent with that reflected on the 'Accompanying Bill', transaction cash flow and transaction value.

For purchase by the distributor:

- A VAT special invoice or general invoice shall be collected and must be issued by the manufacturer.
- The type, specification and quantity of the procured pharmaceutical products shall be in accordance with those shown on the corresponding invoice and 'Accompanying Bill'. Otherwise, the delivery cannot be accepted.

- Records for delivery shall be established to reflect the verification of the information between the product and the related documents.

For medical institution procurement bidding:

- The 'two invoices' system shall be a prerequisite for centralised procurement.
- Pharmaceutical manufacturers shall directly participate in the bidding.
- Commitment to conform to the 'two invoices' system shall be included in the tender or the tender will be nullified.
- If the procurement is not centralised, terms and clauses clarifying the requirements of the 'two invoices' system shall be set out in the procurement contract.

For inventory check and acceptance by medical institutions:

- The received pharmaceutical products shall correspond with the matching invoices and accounting book.
- VAT invoices shall be collected from the distributor and verified.
- A copy of the invoice issued by the manufacturer to the distributor shall be attached to the pharmaceutical products delivered; the official stamp of the distributor shall be affixed on such copy.
- The information (e.g. the name of the distributor and batch number of the products) shown on the two invoices must corroborate.

KPMG China's observations

Circular 4 provides a common platform for the development and implementation of the 'two invoices' system across China. Its clarification of the types of manufacturing enterprise and group company treatment provides flexibility to alternative business models which can be adopted under the 'two invoices' system. However, based on our observations, there are still uncertainties within Circular 4 which may present challenges to business.

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Definition of Pharmaceutical Trading/Distribution Group (“药品流通集团型企业”)

According to Circular 4, for Pharmaceutical Trading/Distribution Groups (“药品流通集团型企业”), intra-group transfer of pharmaceutical products will not be regarded as the issuance of one invoice as defined in the ‘two invoices’ system. This would allow pharmaceutical manufacturers to deal with the headquarters or one of the distributors

within the pharmaceutical distribution group and minimise their administrative burden in terms of invoice issuance and collection. However, Circular 4 did not define what types of distribution companies qualify as Pharmaceutical Trading/Distribution Groups (“药品流通集团型企业”).



The requirement of 'Delivery of VAT invoice along with delivery of goods' and the requirement to have a copy of a VAT invoice issued by pharmaceutical manufacturers to distributors when the distributors make the subsequent sales to medical service providers

Based on our understanding, when pharmaceutical manufacturers sell pharmaceutical products to distributors, the distributors can further sell the products to different medical service providers. According to Circular 4, a copy of the invoice issued by the manufacturer to the distributor shall be attached along with the pharmaceutical products delivery, and the distributor's official stamp shall be affixed to the copy. The information (e.g. the name of the distributor and batch number) shown on the two invoices must corroborate.

This would allow medical service providers more transparency on the ex-factory price from the pharmaceutical manufacturers. In addition, this may have a potential impact on the invoicing arrangement for pharmaceutical manufacturers. At this stage, it is not clear whether the pharmaceutical manufacturers need to break up the VAT invoices into separate ones according to sales

to each medical service provider. While this requirement would appear to be unlikely as such information would not be available at the time of the sale to distributors, pharmaceutical manufacturers should be aware of such requirement and make sure details of the products can be found in the 'Accompanying Bill', VAT invoice and sales summary attached.

Circular 4 demonstrates the government's commitment to the implementation of the 'two invoices' system. Manufacturers and distributors should therefore take steps to be ready for a comprehensive nationwide implementation of the 'two invoices' system.



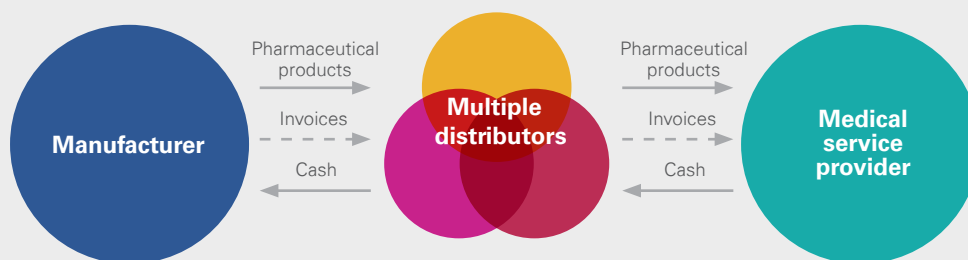


Business and financial impacts of Circular 4 on pharmaceutical companies

The 'two invoices' system will likely have a profound impact on pharmaceutical companies from a business and tax perspective. Based on Circular 4 and the policies implemented in certain regions of China, we explored the financial and tax implications of the 'two invoices' system for pharmaceutical

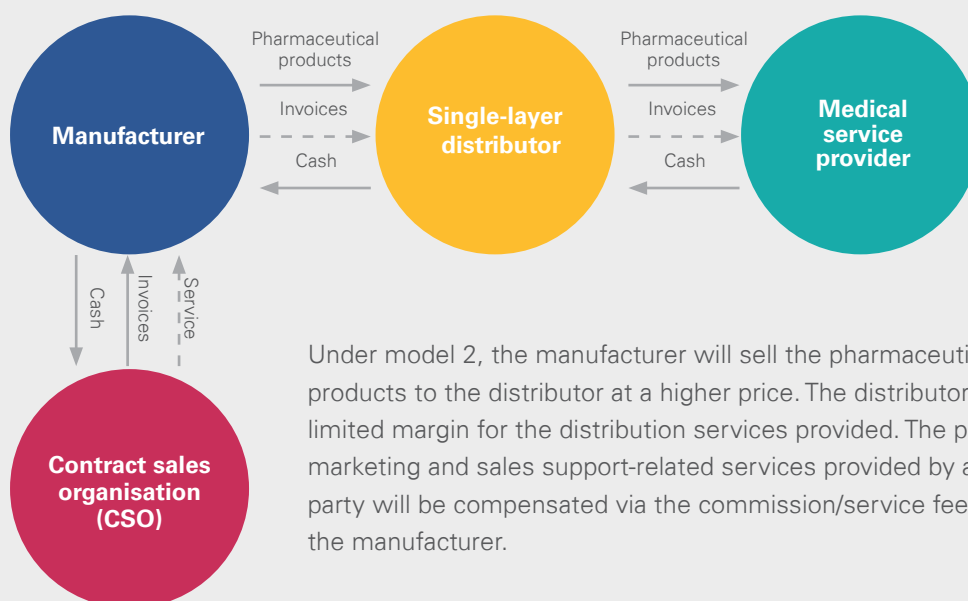
companies in China. Before we look at the impact of this system on the business, we need to first try and understand the current business model adopted by pharmaceutical companies. The current common business models of pharmaceutical companies can be depicted as follows:

Model 1: Buy-sell model



The manufacturer will sell the pharmaceutical products to the distributor at a relatively low price. The margin retained in the distribution channel will be used to cover the promotion, marketing and sales support-related services provided by the distributors. Under this model, the pharmaceutical products will be sold through multiple distributors before being sold to the medical service provider at a much higher price.

Model 2: Commission/service fee model



Under model 2, the manufacturer will sell the pharmaceutical products to the distributor at a higher price. The distributor will earn a limited margin for the distribution services provided. The promotion, marketing and sales support-related services provided by a third party will be compensated via the commission/service fee paid by the manufacturer.

Due to the implementation of the 'two invoices' system, model 1 will be phased out as there will only be one distributor allowed in the value chain going forward. As such, any service providers that currently exist in the supply chain will need to be compensated separately through the commission/service fee arrangement. It is expected that more and more service providers will become specialised Contract Sales Organisations (CSO) as shown in model 2 above. It can also be foreseen that large distribution organisations will carve out a sales support division and put that into a separate legal entity to comply with the 'two invoices' system.

While pharmaceutical manufacturers adopt model 2 to comply with the 'two invoices' system, consideration should be given to the following aspects:

Business impact:

- Channel management for pharmaceutical companies would change from a hierarchical structure to a flat structure. Pharmaceutical companies may have to engage different distributors in each province based on the authorised distributor list of each province. More specifically, in some remote areas where the first-tier distributor does not have a direct presence, pharmaceutical companies would need to deal directly with the distributors in those locations. This will increase the number of distributors to be managed by the pharmaceutical company.
- There will be less invoice 'pass-through' arrangements due to the two invoice limitation. As such, many of the smaller/regional distributors would be acquired by large distributors or forced out of business.

Financial impact:

- For those pharmaceutical companies currently operating under model 1, there are inventories maintained by distributors throughout the supply chain. Before the implementation of the 'two invoices' system, there is a need to clear those inventories from the supply chain. This will have an impact on pharmaceutical companies' sales in the short term.
- According to Circular 4, the distributor is required to submit the invoice issued by the manufacturer or importer to the hospitals. This requirement will help ensure that pharmaceutical products delivered to the hospitals are the same batch sold by the manufacturer or importer. It also makes the ex-factory price or selling price of the importer transparent to the hospitals. The hospitals procure the pharmaceutical products based on the predetermined price through the bidding/negotiation process. Currently, the price differences between the ex-factory price and the hospital purchase price are much greater than the normal margins earned by a pure distributor. The challenge to the manufacturer is how to determine its ex-factory price under the 'two invoices' system.
- If the manufacturer decides to increase its ex-factory price to match the purchase price of the hospital (excluding the distributor fee), it may represent a significant upwards adjustment of its selling price. The increase of its selling price will lead to a higher VAT payable by the drug manufacturer. While the tax authority would most likely welcome such increases, it may also raise questions about the price fluctuation, and in particular, the lower price adopted in the past.



- If the manufacturer decides not to increase its ex-factory price, the 'two invoices' system would disclose such ex-factory price to the hospital, which may demand a reduction in the purchase price. This can help achieve the objective of lower drug prices set by the healthcare reform. However, this will likely lead to lower margins earned by the drug manufacturers if they have to pay the CSOs for the marketing and promotion services provided. This drop in operating margin will likely attract an immediate enquiry from the tax authority. In order to maintain the target operating margin under its current transfer pricing model, the drug manufacturer may look to adjust the transfer pricing arrangement with its overseas supplier, either from the import price of active pharmaceutical ingredients (API) or other key components required for its operation in China.
- The CSO plays an important role in the promotion and marketing of the pharmaceutical products to hospitals and doctors. Typically, the commission/ service fee of the CSO will be calculated as a percentage of the sale of a particular drug. There is a question of whether such fees would be treated as commission and subject to a 5 percent deduction limit for commission expenses under the Corporate Income Tax law. The genuine business substance of the commission/ service fee should also be analysed from a compliance perspective.
- For imported pharmaceutical products, most of the MNC pharmaceutical companies will engage a third-party logistics service provider to act as the importer and distributor of the imported pharmaceutical products due to the distribution licence restriction in China. If there are currently more than two



invoices in the distribution channel, i.e. from the importer to the hospital, some of the distributors in the supply chain will be eliminated. If those distributors also provide marketing and sales support services, they will need to be compensated by the overseas products owner directly.

- However, whether the overseas pharmaceutical companies are willing to engage directly with such service providers in China would depend on their assessment of the qualification and compliance status of the service provider. Therefore, it is likely that more MNC pharmaceutical companies will bring marketing and sales support services into their own subsidiaries in China for better management of such activities.
- The exact level of compensation to the related-party CSOs or consultancies will depend, to a large extent, on the nature of activities that will be carried out by the CSOs or consultancies. If the CSOs' activities are akin to what would historically be carried out by the multiple layers of distributors and will contribute directly to the sales of drugs, tax authorities are more likely to argue for commission-based pricing. If, on the other hand, such CSOs or consultancies' activities are more ancillary or supportive in nature, a cost-plus arrangement may suffice. That being said, the 'two invoices' system will have a great impact on the commercial landscape of the pharmaceuticals industry in China, and companies' transfer pricing adjustments must adapt to the changing business environment.
- In order to better manage the distribution of imported pharmaceutical products in China, some MNC pharmaceutical

companies are looking for ways to acquire a Good Supply Practice (GSP) licence. If they are successful, it will consolidate the importation and sale of the imported pharmaceutical products with the marketing and sales support activities into one commercial legal entity. While this brings greater control to the management and distribution activities in China, such change presents more challenges when commercial companies with GSP licences try to minimise the fluctuation of the import price, meeting the targeted operating margin for tax purposes and achieving a reasonable selling price to the hospitals.

- These considerations send conflicting signals for the determination of the transfer price between the overseas product owner and the Chinese commercial company. Approaching this in a holistic manner and holding advance consultations with the relevant government authorities would be critical in order to minimise further audits of/ enquiries about the transfer pricing arrangement of the commercial company.

Conclusion

Circular 4 demonstrates the government's commitment to the implementation of the 'two invoices' system. Hence, manufacturers and distributors should proactively prepare themselves for a comprehensive nationwide implementation of the 'two invoices' system, which will likely have a profound impact on pharmaceutical companies from a business and tax perspective.

It is conceivable that whatever means enterprises employ to fulfil the shifting regulatory requirements would demand a well-coordinated approach to managing the fast-changing landscape. The resulting impacts could be far-reaching, with a wide range of interested parties involved. At the internal level, this includes business, sales, treasury, compliance, legal, government affairs and even project management; at the external level, it involves platform service providers, distributors, medical institutions and others, which will also see significant influences.

Given its strategic importance and complexity, we suggest that a cross-functional taskforce be put together, which will cooperate to develop an in-depth understanding of the updated policies, and respond promptly. The taskforce is expected to help the enterprise better navigate the shifting regulatory landscape and mitigate any associated risks.

From a tax perspective, management is recommended to review and prepare for the ensuing tax implications brought by the changes in the business model, including those on transfer pricing and service fees related to promotion activities. We believe taking the initiative to pre-empt any possible challenges or threats can help the enterprise rebuild business channels and regain momentum.



Appendix I

Provinces which have implemented the 'one invoice' or 'two invoices' system, and the timeline



PROVINCES WHICH HAVE IMPLEMENTED THE 'ONE INVOICE' OR 'TWO INVOICES' SYSTEM, AND THE TIMELINE

Province	Policy	Timeline	Whether the province falls under the trial comprehensive healthcare reform plan
Fujian	Fully implement 'two invoices' system	End of 2014	First batch
Zhejiang	Implement 'one invoice' system: information, commerce and funding combined into one channel	1 July 2016	Second batch
Hubei	Implement in Wuhan, Xiangyang and E'zhou	August 2016	No
Anhui	Partially modify and adjust the 'two invoices' system, including the definition of 'manufacturer', and the policy that one extra invoice can be issued for drug procurement for rural public hospitals	1 November 2016	First batch
Shandong	Implement in six cities: Jinan, Qingdao, Dongying, Weifang, Weihai and Binzhou	November 2016	No
Qinghai	Implement in public hospitals across the whole province. Grassroots medical institutions can issue one more invoice during the sale and procurement of medicine, and the 'two invoices' system is gradually being implemented.	15 December 2016	First batch
Sichuan	Implement in public hospitals in parts of districts	31 December 2016	Second batch
Shaanxi	Implement the 'two invoices' system in urban public hospitals while keeping the current distribution model unchanged in the rural areas; promote the 'one invoice' system	1 January 2017	Second batch
Hunan	Implement the 'two invoices' system with modifications	1 January 2017	Second batch
Hebei	Implement the 'two invoices' system in all public medical institutions, with modifications	1 May 2017	No
Chongqing	Implement the 'two invoices' system across the municipal city	1 June 2017	Second batch
Guangdong	Gradually implement the 'two invoices' system	From 2017	No
Ningxia	Implement the 'two invoices' system and promote the 'one invoice' system	2017	Second batch
Tianjin	Implement the 'two invoices' system and promote the 'one invoice' system	2017-2020	No
Heilongjiang	Implement the 'two invoices' system across the 63 county hospitals and above	Not yet indicated	No
Guizhou	Implement the 'two invoices' system	2017	No



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