

Chinese Government Issues Policy to Slim Distribution Chain of Pharmaceuticals

“Two-Invoice System” Aims to Reduce Prices and Corruption

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Food, Drugs, and Devices

On January 9, 2017, eight Chinese ministries announced a significant new policy that aims to reduce marked-up prices and corruption in multi-tier distribution chains. The policy effectively requires that under most circumstances, at most two invoices may be issued throughout the distribution chain, with one from the manufacturer to a distributor and another from the distributor to the end hospital. The policy applies only to drugs, but some provinces reportedly have been implementing similar policies for medical devices.

Seven central ministries¹ joined the National Health and Family Planning Commission to issue the new policy, described in the *Notice on the Distribution of the Opinions on the Implementation of the ‘Two-Invoice System’ in Drug Procurement by Public Medical Institutions (for Trial Implementation)* (the “Two-Invoice [Notice](#)”). Covington’s translation of the Notice is [here](#). The Notice takes effect from the issuance date.²

Drug manufacturers using complex, multilayer distribution chains will likely be required to revamp their distribution models to comply with this change. This alert sets forth the analysis and information on implementation of the Two-Invoice System in the drug procurement by public medical institutions (“Two-Invoice System” or the “System”).

Background

The Two-Invoice System, which has been under discussion for several years, is part of a larger reform of the healthcare system set forth in the 13th Five-Year Plan on Deepening Reform of the Medical and Healthcare System. The State Council released that plan on December 27, 2016. Among its other goals, this Five-Year Plan aims to establish a more regularized and procedure-oriented supply chain for drugs with process reforms for manufacturers, distributors and user entities. The goal is to ensure a steady supply of safe and effective drugs with lower prices.

¹ The other ministries jointly issuing the Notice have important roles in the drug regulatory system, such as the Medical Reform Office of the State Council, the China Food and Drug Administration, and the National Development and Reform Commission.

² The Notice appears to have been signed by the agencies on December 26, 2016, but it was not published until January 9, 2017.

Purpose of the Two-Invoice System

The Two-Invoice System aims to reduce drug prices and corruption that can occur in lengthy distribution chains between the manufacturer and the end-user hospital. The Notice states that the policy is to “regulate the order of drug distribution, reduce distribution links, and lower the unreasonably high drug prices” and act as “an effective measure to clean up the distribution environment, crack down on ‘money-laundering by invoice fraud’, and strengthen the regulation of the pharmaceutical market.”

In practice, certain drug and device manufacturers and distributors have long been using multiple intermediates (or small local distributors) to distribute their products. One reason for this multilayer model is to leverage the local distributors’ connections or networks to reach certain hospitals. However, the long distribution chains can also serve as a screen for increased margins and multiple invoices—sometimes fraudulent or inflated—to make illegal payments to officials and physicians to boost sales.

Details of the System

The Two-Invoice System means that during the distribution process from a drug manufacturer to the hospital there may be only two tax-valid invoices (or *fapiao*³). One invoice is issued by a manufacturer to a distributor, and another invoice is issued by the distributor to a hospital.

The Notice articulates several exceptions to the Two-Invoice System. First, a wholly owned or wholly controlled commercial company established by a pharmaceutical group that only sells the drug of that group (limited to one commercial company in China) or the exclusive distributor of imported drug products in China (limited to one) may be deemed a “manufacturer.” Therefore, the Two-Invoice System would not apply to the sale of the products from a manufacturer to a commercial company within the same group or from an imported drug manufacturer to its exclusive distributor in China, because that is not considered “distribution” and is only a transfer between manufacturers. The System would apply to subsequent transactions.

Second, an internal “transfer”⁴ of drug products from a pharmaceutical distributor to its wholly owned (controlled) subsidiary or between wholly owned (controlled) subsidiaries of that distributor is not counted as a separate invoice for purposes of the Two-Invoice System. However, no more than one invoice may be issued for such internal transaction. It remains to be seen how this should be interpreted and carried out in practice.

The Notice seems to suggest that an additional invoice, in addition to the “Two-Invoices”, would be permissible if distribution is to a “remote” township or village. It is not clear how this would work or what constitutes a “remote” area.

³ For more about *fapiaos* in China, particularly how they can be misused for fraud and corruption, please see Covington’s article [here](#).

⁴ The Chinese word used is “調撥”, which literally means “moving around”. It is unclear whether this choice of word means that the contemplated intra-company group transactions here are something different from the usual buy/sale transactions between group companies.

The Notice also sets forth requirements for distribution companies and hospitals to review invoices. Distribution companies must carefully check invoices from manufacturers against details of the products, and hospitals must do the same for the invoice from distributor and photocopies of the manufacturer's invoice. The hospital must compare the two sets of invoices. The practical effect of this requirement will be to give hospitals visibility over the margins enjoyed by distributors.

Implementation of the Policy

The Two-Invoice System will first be implemented in the 11 provinces that are involved in pilot comprehensive medical reforms and 200 cities for pilot public hospital reform. The provinces are Anhui, Chongqing, Fujian, Hunan, Jiangsu, Ningxia, Qinghai, Shaanxi, Shanghai, Sichuan, and Zhejiang. All other regions are *encouraged* to implement the Two-Invoice System. The Notice indicates the objective is for nationwide implementation to occur by 2018.

In areas where the System will be implemented, public hospitals are required to “gradually” implement the “Two-Invoice System.” while all other types of hospitals are *encouraged* to implement the System. Compliance with the Two-Invoice System will become a prerequisite for participation in procurement processes with public hospitals. For procurement through bidding, the manufacturers must participate in the bidding directly (rather than entrusting distributors to do so on their behalf), and the manufacturers are required to represent that they are compliant with the Two-Invoice System.

Pharmaceutical manufacturers and distributors that fail to implement the Two-Invoice System may lose their qualifications to participate in the bidding process, win a bid, or distribute drug products. Non-compliant manufacturers may also be blacklisted from engaging in drug sales to public hospitals in a locality.

The Notice states that the government supports major pharmaceutical distributors with comprehensive networks and reputations for quality, as well as the establishment of national and regional drug logistics parks and distribution centers. However, it is not clear what benefits distributors that meet this description and/or participate in these parks would acquire. The practical effect would be to continue the trend of centralizing distribution in a handful of pharmaceutical distributors, many of which are state-owned or state-controlled.

Implications for Compliance with Anti-monopoly Law

The National Development and Reform Commission has long focused on vertical anti-competitive conduct, such as retail price maintenance (“RPM”), in the pharmaceutical and medical device sectors. On December 7, 2016, it fined Medtronic (Shanghai) Management Co., Ltd. RMB 118 million (about \$17.3 million) for engaging in RPM and other vertical restraints. Medtronic, which used a multilayer distribution system in China, was found restricting the resale prices of its distributors at all levels, despite the fact that these distributors are independent market players rather than Medtronic's affiliated entities.

With the implementation of the Two-Invoice System, resale prices will be more transparent because end hospitals are required to compare the two sets of invoices when procuring drugs. Thus, it is even more important for drug manufacturers to comply with the Anti-Monopoly Law and not restrict the resale prices of their distributors.

Conclusions and Future Considerations

The Two-Invoice System may bring significant reform to existing distribution practices and business models that drug and device companies have been using in China.

Each manufacturer will need to assess their distribution models in China with this new policy in mind, and make necessary adjustments to minimize their compliance risk accordingly. Companies that have been using a “multilayer” distributor model would need to revamp their business model to comply with the Two-Invoice System. The Notice does not provide clear guidance on how fast this would need to occur, besides simply requiring that the public hospitals should “gradually” implement the Two-Invoice System.

The Two-Invoice System could trigger a new round of mergers and acquisitions and company integration among the distribution companies, and some manufacturing companies may also take the opportunity to build up their distribution capacity through acquisitions.

From a healthcare policy standpoint, the System could reduce protectionist procurement practices in the provinces. This could facilitate the flow of drugs and devices to patients and ultimately make the bidding processes fairer.

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