“Two-invoice System” — Survive through Change and Develop through Exploration

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Making another century of impact
On January 11, 2017, the State Council Healthcare Reform Office, the National Health and Family Planning Commission of the People’s Republic of China, the FDA as well as another six ministries and commissions issued the so-called GYGBF [2016] No.4, 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 purpose has been to establish detailed implementing rules for the policy according to local conditions and to create quick reports to the Medical Reform Office of the State Council.

As a professional third-party institution, Deloitte – with its long-lasting track record in providing expert advisory services in risk, strategy and tax to customers from the Life Sciences and Healthcare industry – uses its leading methodology to offer customers a detailed analysis of the new policy. The purpose of this article is to show the background of the new policy, features of industries affected and measures to encounter these changes.

1 Policy Background

1.1 Policy History
In 2007, the Health Department of Guangdong Province issued the Implementing Plan for Transparent Drug Procurement in Healthcare Institutions in Guangdong Province (First Draft) and put forward the notion of the Two-invoice System for the first time. But the plan failed to survive for various reasons. In 2009, the Ministry of Health and five other ministries jointly issued the Opinions on Further Regulating Centralized Procurement of Drugs for Public Hospitals (WGCF [2009] No.7) (the Opinions), which has finally come into effect. The aim of the Opinions was to “reduce distribution layers”, specifying that “drugs shall be delivered to healthcare institutions directly by manufacturers or medical enterprises having the capability of performing modern logistic, and such delivery shall be delegated, in principle, no more than once”.

In accordance with the Opinions, the Ministry of Health of Fujian Province and other seven departments jointly issued in 2009 the Implementing Opinions on Further Regulating Centralized Procurement of Drugs for Healthcare Institutions (M2B [2009] No.140) to “reduce distribution layers and require unified distribution”. At the same time, Fujian became the first province to introduce the Two-invoice System in 2010.

1.2 Recent Development
On April 6, 2016, Premier Li Keqiang chaired the State council executive meeting and pointed out key areas in deepening the structural reform of the medical and healthcare system. For the first time, he introduced the concept of the Two-invoice System (one invoice between manufacturers and distributors; one invoice between distributors and medical institutions) with the aim to increase transparency. On April 26, the State Council issued the Key Tasks of Deepening the Medical and Health System Reform in 2016 (GBF [2016] No. 26), requiring the implementation of the Two-invoice System throughout provinces that had carried out the pilot policy of the comprehensive reform of public hospitals. Subsequently, this has encouraged cities under this pilot policy to follow suit. On November 8, the Office of the Leading Group for Deepening Reform of the Medical and Health Care System of the Ministry of Health issued the Opinions of the CPC Central Committee and the State Council on Deepening the Reform of the Medical and Health Care System, introducing a gradual reform of the Two-invoice System among public hospitals.

On January 11, 2017, the State Council Medical Reform Office and seven other departments jointly issued the Opinions on the Implementation of the “Two-invoice System” in Drug Procurement by Public Medical Institution (for Trial Implementation) (GYGBF [2016]) No.4 to promote the gradual introduction of the Two-invoice System in full swing by 2018.

Having been accepted and promoted by the central government in recent years, the Two-invoice System evoked considerable actions across certain areas. According to our knowledge, a total of 11 provinces have issued documents for the policy, listed in detail as follows:

- **Fujian**: Since 2010, Fujian has fully implemented the policy.
- **Jiangsu**: In April 2016, Jiangsu Food and Drug Administration issued a consultation paper for the policy.
- **Zhejiang**: In April 2017, the Provincial Healthcare Reform Office issued the Implementation Plan of the “Two-invoice System” in Drug Procurement of Zhejiang Provincial Medical and Healthcare Institutions (a consultation paper). The implementation of the Opinion will start since June 1st, 2017, with the transition period of five months.
- **Hunan**: In June 2016, the provincial government issued the Pilot Plan for Deepening the Comprehensive Reform of the Medical and Healthcare Industry in Hunan Province (XZF [2016] No.12) to promote the Two-invoice System.
- **Sichuan**: In April 2017, the provincial government issued the Implementation Plan of the “Two-invoice System” in Drug Procurement of Sichuan Provincial Medical and Healthcare Institutions (for Trial Implementation). The policy covers all public medical and healthcare institutions in the province barring institutions in ethnic, poverty-stricken and remote areas and basic institutions in other areas, with the transition period of five months.
• **Shaanxi**: In March 2017, Shaanxi eight departments jointly issued the Notice on the Distribution of the Opinions on the Implementation of the “Two-invoice System” in Drugs and Medical Consumables by Public Medical Institutions. The Notice states that delivering medical consumables has to implement “Two-invoice System”, but high value consumptive material can be firstly in trial if having difficulties in overall implementing process.

• **Anhui**: In October 2016, Anhui Food and Drug Administration issued the Opinions on the implementation of Two-invoice System in Drug Procurement in Public Healthcare Institutions in Anhui Province (WSYJYHL [2016] No.37) to promote the policy across the province.

• **Qinghai**: In December 2016, the General Office of Qinghai Province issued the Opinions on the Implementation of the Two-invoice System in Drug Procurement in Public Healthcare Institutions in Qinghai Province (for Trial Implementation) to promote the policy.

• **Chongqing**: In December 2016, the Municipal Health and Family Planning Commission and other eight departments jointly issued the Implementation Scheme of the Two-invoice System in Public Healthcare Institutions in Chongqing (for Trial implementation), requiring the implementation of the policy in all public healthcare institutions across the city before June 1, 2017.

• **Liaoning**: In April 2017, Liaoning issued the Implementation Details of the Two-invoice System in Public Healthcare Institutions in Liaoning (for Trial Implementation). It states that the public medical institutions at all levels have to implement the two-invoice system since June 1st, with a preparation period of three-month. Since August 1st the carding channels should be optimized, and since September 1st the Implementation Details should be formally implemented.

• **Shanxi**: In April 2017, Shanxi issued the Implementation Details of the Two-invoice System in Public Healthcare Institutions in Shanxi (for Trial Implementation). It implements since May 1st with the transition period of five months. It also clearly forbids technology companies, consulting companies and other non-pharmaceutical enterprises to promote and sell drugs.

• **Gansu**: In April 2017, Gansu eight departments jointly issued the Implementation Scheme of the Two-invoice System in Public Healthcare Institutions (for Trial Implementation), requiring the implementation of the policy before 2018 with the transition period of four to five months.

With the continuing support for the policy from the State Council, provinces will be further encouraged to make faster progress in implementing the policy.
2 Impact Analysis

2.1 Pharmaceutical Industry

In order to analyze the policy’s impact on the pharmaceutical industry, we distinguish between the distributions of three major products: special drugs, vaccines and regular drugs.

Special drugs (psychotropic drugs, narcotic drugs, toxic drugs and radioactive drugs): As a result of strict regulatory and special certification requirements by the CFDA, there has been a relatively fixed list of distributors for these so-called special drugs, most of the distributors being tier one suppliers serving hospitals directly. Therefore, the new policy will have limited impact on the distribution of special drugs.

Vaccine: As a result of the notorious “toxic vaccine” incident, effective progress has been made in the transformation of the two-invoice or one-invoice system in accordance with Article 14 and Article 13 of the newly revised Regulation on the Administration of Circulation and Vaccination of Vaccines. More precisely, the regulation states that “vaccine production enterprises shall directly distribute Class-II vaccines to county disease prevention and control institutions or authorize enterprises with cold chain storage and transport conditions to distribute them” and “a vaccine production enterprise shall, according to the stipulations in the government procurement contract, supply Class-I vaccines to the disease prevention and control institutions at the provincial level or other disease prevention and control institutions designated by the aforementioned institutions, and shall not supply Class-I vaccines to any other entities or individuals.”

Drugs: The new policy has a considerable impact on the drug distribution. Manufacturers will be particularly affected by the new policy, but also distributors with GSP certificates will feel its impact. More precisely, due to the policy’s rapid implementation without detailed requirements, manufacturers will encounter substantial problems, while not having many other options left. Some of them, presumably those with control over the terminal distribution, may ascend to be tier one distributors, however having to face compliance, operational cash flow and external cooperation issues. Moreover, manufacturers need to consider several reform measures, reconsidering how to upgrade their dealers, integrate their business teams, optimize internal processes, reform CSO (Contract Sales Organization) review standards and adjust their KPI assessment.

2.2 Medical Instruments

The policy's impact on medical instruments can be broken down into three components: the impact on medical device, high value consumptive material and low value consumptive material, discussed as follows.

Medical device: Hospitals purchase medical device through a bidding process, while CSO agents are responsible for its distribution and promotion. Agents usually deliver device directly to hospitals, while manufacturers provide technology support. The use of this model, allows both parties to easily meet the requirements of the Two-invoice System. However, the multi-level, loose and opaque structure of agents poses significant risks for manufacturers. In addition, because of the overwhelming position of agents, manufacturers may unknowingly receive device from subagents or distributors. Therefore, understanding the whole operation environment and knowing in detail delivery processes and the invoice issuance procedure is of major importance.

Low value consumptive material: Due to its low price and huge quantity, there has been a mature environment for its procurement so that hospitals usually choose to purchase low value consumptive material through a bidding process. At present, its distribution process is relatively quick. However, the scattered distributors and high management costs pose a heavy burden on the shoulders of hospitals. Notably, its distinct requirements for storage, restricts the hospitals' choice of distributors.

High value consumptive material: Due to its own complexity, high value consumptive material is particularly affected by the Two-invoice System. Manufacturers do not only rely on their own teams but also on outsourcing vendors. Besides, high value consumptive material differs substantially from others, since some material, such as artificial joints, is directly applied for operational use. At present, due to its complexity of the distribution structure and the fact that many distributors play the role of agents at the same time, there will be much more difficulties in transformation and channel integration to be tackled. Meanwhile, with the extensive use of high value consumptive material by CSOs, distributors must seize the chance for the transformation of tax planning and financial planning. In addition, following strictly the detailed requirements by CSOs is another challenge that must be overcome.
2.3 Formula Food for Special Medical Use
On March 10, 2016, the government issued the Measures for the Administration of the Registration of Formula Food for Special Medical Use, shedding some public light on this specific kind of products. According to Article 6, registration and standards for formula food should reference to those of regular food. More precisely, the article states that “CFDA shall be responsible for building up an expert panel for the evaluation of Formulas for Special Medical Purpose. The expert panel consists of experts in food nutrition, clinical medicine, food safety, food processing and other fields.” However, hospitals mainly purchase special food from pharmaceutical distributors and face significant difficulties in opening accounts. Besides, its special medical use has rather labeled it as a medical supply. Hence, before the introduction of a more detailed policy, suppliers may learn from the experience of GSP and come under regulation, but it will still take some time until we know whether these products will be affected by the new policy.

As we have seen, the policy change has a major impact on nearly every product line across the whole industry, so that a sound strategy is crucial.

3 Strategies

3.1 Internal Operations Diagnostics
Under the Two-invoice System, the entire industry may change whole business models. Therefore, enterprises must have a comprehensive understanding about their own business structure before drawing too hasty conclusions.

We recommend short-term, in-depth, and fast internal operations diagnostics to help enterprises gain further insights into their internal environment. Such diagnostics help to quickly understand the overall foundation for transformation and the transformation costs caused by changes of business procedures and systems. Thus, an in-depth understanding, allows enterprises to lay a solid foundation for a backup strategy.

3.2 Update the Distribution Management Model

The introduction of the Two-invoice System will affect distributors the most. According to the current market situation, we recommend an overall review of actual flows of goods, especially those of medical device. Moreover, it needs to be considered that the long-standing existence of subagents may draw a veil over the real flow of goods.

In addition, many distributors have secured the purchasing rights of some terminal institutions, which will cement their position for a longer while. Thus, subagents may seize the chance to become direct agents. However, due to a historical distance between distributors and enterprises, distributors should try to have an in-depth understanding about enterprises’ compliance and cash flow conditions.

At the same time, enterprises must develop a reasonable standard for the upgrading of distributors. However, upgrading a great number of downstream distributors may bring challenges to commercial, financial and compliant issues.
3.3 Optimization of Internal Tax Planning and Financial Strategy
As a result of the introduction of CSOs, the establishment of the sole import agent, and certain consequences of imported goods, manufacturers may consider stopping overseas business, leading to a change of overall financial operations and tax planning.

In response to this situation, we recommend an overall advisory on tax and legal issues. The Two-invoice System causes an upending transformation, so that there is not only a separate integral issue to be solved. The transformation will not only impact the CSO settlement but also affect extra financial costs by the enterprise itself and the overall revenue recognition procedure.

3.4 Conclusion
As mentioned above, the Two-invoice System will have a considerable impact on the whole industry, and enterprises also need to have in-depth understanding of themselves, gain insights of the new policy, and make solid adjustments at every single stage to embrace the change.

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