

## Medical Device Loans: Transparency is Key to Anti-Corruption

Medical device firms have long been targets of anti-bribery investigations in China. Many of them have designed and implemented stringent compliance policies to prevent typical corruption conducts such as kickbacks and luxurious entertainments. However, this does not remove them from regulators' attention: in recent years, many medical device firms are facing investigations on business activities that are not traditionally seen as bribery. One example is the rental-free equipment loan arrangement.

### Business Model

Equipment loans are common in the medical device industry because hospitals are often unwilling or incapable of paying the full price or event rents of the device at a market rate, so a medical device firm may offer an option of obtaining the loan of equipment for free or at heavily discounted rent, provided that the hospitals hit certain annual supply and purchase targets. This business model has often been used to promote newly developed devices, or to encourage hospitals to purchase more consumables associated with the loaned equipment.

Some medical device firms have recently become alert to the risks of directly leasing equipment to hospitals for free. In order to keep a clear record on their own books, they instead lease the equipment to distributors at the fair market rental value, leaving it to the distributors' discretion whether to exempt hospitals from paying rent. Predictably, distributors often have incentives to provide a rental-free loan arrangement to hospitals.

### Legal Risks

On the face of it, this business model may appear to be justifiable. The benefits are given to the hospital, instead of any individuals making the purchase decisions for or on behalf of the hospital. Further, this arrangement is usually not entirely under the table, but is reflected in contracts or the medical device firms' sales / reward policies.

Despite these justifications, this arrangement has been challenged by local regulators, in particular, the local primary regulators of commercial bribery, the administrations for industry and commerce (AIC). In some AICs' view, the benefits of the equipment loan are not and cannot be accurately reflected in books and records. A few AICs further assert that as no rent has been paid, hospitals are able to evade tax liabilities for the benefit of using the loaned equipment; they reason that medical device firms are effectively facilitating such tax evasion, which is an illegitimate benefit, or a bribe, in their view. Interestingly, this point is often made not by tax authorities, but by AICs.

In addition, it is not uncommon for the medical device firm to tie this rental-free arrangement to sales of its own consumables. Depending on the medical device firm's market share, this has been viewed as a bundling arrangement and thus, raises exposure to anti-trust investigations. The risk is further enhanced if this tie-in arrangement is exclusive (i.e., only the same firm's consumables can be used in its loaned equipment).

The practice of granting the loan through distributors is not risk free either. Local regulators may find, despite the indirect transaction, evidence or inferences that a medical device firm is or should be aware of the rental-free equipment loan arrangement between its distributors and end users (i.e., hospitals). If so, they will conclude that the medical device firm is part of a conspiracy. Under the U.S. Foreign Corrupt Practices Act ("FCPA"), absence of actual knowledge under these circumstances may not provide a valid defence, as this may be seen as a conscious avoidance (also known as "wilful blindness" or "deliberate ignorance").

## Practical Solutions

The most straightforward solution is to abandon the rental-free business model. In a perfect scenario, a medical device firm should lease the equipment to hospitals for rent at market rate, accurately record the rent in its books, and properly issue taxed invoices. If a distributor is engaged, the medical device firm should further require an undertaking by the distributor that the latter will also charge rents at market rate on hospitals. The firm may also reserve a right to audit the distributors and regularly, exercise such right. These measures will minimize the risks of any rental-free arrangement between the distributor and hospitals, and even if there is such an arrangement, provide the medical device firm with a strong defence against liability.

However, this solution might be impractical under certain circumstances. High rents may deter hospitals from using newly developed or expensive equipment, and medical device firms may lose a strong tool to encourage or reward purchase from hospitals. Is there a way to take the cream and discard the dross of this business model?

Maybe. In fact, the PRC laws do not generally prohibit discounts and rebates. Rather, the laws require only that discounts and rebates are explicitly documented in contracts and accurately recorded in the firm's books. Therefore, one possible option is to explicitly and separately agree under the contract (1) volume-linked discounts and rebates on sales to distributors or hospitals, and (2) rents at market rate. Then, one would adopt a properly-documented arrangement to set off the discounts / rebates and the rents. The amount of rents and discounts / rebates should be clearly specified in the contract, and accurately recorded on every party's respective books.

With respect to the anti-trust risks of the tie-in arrangement, it is advisable to, if technically feasible, avoid exclusive bundling arrangements and to shorten the term of the equipment loan agreement so as to provide hospitals with more flexibility in choosing alternative suppliers.

## Conclusion

New business models are developed from time to time to encourage sales. These business models may carry bribery risks even if they are not readily apparent, so careful review from an anticorruption perspective is required. Overall, transparency and accurate recording are always the key to mitigating the risk of corruption suspicions.

## Contacts



**Wendy Wysong**

**Partner**

T: +852 2826 3460 (Hong Kong)  
+1 202 290 7634 (Washington)  
E: wendy.wysong@cliffordchance.com



**Kabir Singh**

**Partner**

T: +65 6410 2273  
E: kabir.singh@cliffordchance.com



**Diana Chang**

**Partner**

T: +61 28922 8003  
E: diana.chang@cliffordchance.com



**Jenni Hill**

**Partner**

T: +61 8 9262 5582  
E: jenni.hill@cliffordchance.com



**Michelle Mizutani**

**Counsel**

T: +81 3 5561 6646  
E: michelle.mizutani@cliffordchance.com



**Yu Bing**

**Counsel**

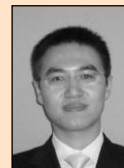
T: +86 21 2320 7372  
E: bing.yu@cliffordchance.com



**Montse Ferrer**

**Registered Foreign Lawyer**

T: +852 2826 3562  
E: montse.ferrer@cliffordchance.com



**Lei Shi**

**Senior Associate**

T: +852 2826 3547  
E: lei.shi@cliffordchance.com

This publication does not necessarily deal with every important topic or cover every aspect of the topics with which it deals. It is not designed to provide legal or other advice.

Clifford Chance, 27th Floor, Jardine House, One Connaught Place, Hong Kong  
© Clifford Chance 2014  
Clifford Chance

[www.cliffordchance.com](http://www.cliffordchance.com)

Abu Dhabi ■ Amsterdam ■ Bangkok ■ Barcelona ■ Beijing ■ Brussels ■ Bucharest ■ Casablanca ■ Doha ■ Dubai ■ Düsseldorf ■ Frankfurt ■ Hong Kong ■ Istanbul ■ Jakarta\* ■ Kyiv ■ London ■ Luxembourg ■ Madrid ■ Milan ■ Moscow ■ Munich ■ New York ■ Paris ■ Perth ■ Prague ■ Riyadh ■ Rome ■ São Paulo ■ Seoul ■ Shanghai ■ Singapore ■ Sydney ■ Tokyo ■ Warsaw ■ Washington, D.C.

\*Linda Widyati & Partners in association with Clifford Chance.