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Donations and Grants in China: Compliance Controls Beyond T&E

While travel and entertainment expenses have presented significant compliance challenges for life sciences companies operating in China, donations and grants can also pose notable compliance risks. China's escalated anti-corruption enforcement in recent years is well-publicized, and regulators have taken interest in grants and donations in the life sciences space. For example, in early 2015, the State Administration of Industry and Commerce ("SAIC"), which enforces commercial bribery regulations, published specific guidance on this issue for the pharmaceutical industry. More recently, the National Health and Family Planning Commission ("NHFPC"), China's regulator for the health care services sector, also enacted specific measures on donations for health care-related organizations. These trends suggest potential scrutiny from enforcement officials towards grants and donations, which may be areas that deserve additional attention from legal and compliance professionals in the life sciences sector.

I. New NHFPC Regulations on Donations

On October 20, 2015, the NHFPC published *Measures for Administering the Receipt of Public Welfare Donations by Health and Family Planning Organizations* ("New Measures"). Despite being announced in October, the New Measures became effective as of August 26, 2015, and replaced the previous measures enacted in 2007, entitled *Interim Measures for the Administration of the Acceptance of Social Donations and Financial Aid by Health care and Health Institutions* ("Old Measures").

The New Measures apply to donations received by hospitals, health care institutions and other health care organizations (*e.g.*, medical associations, funds and charities) overseen by the NHFPC, regardless of whether the donations are made by domestic or foreign life sciences companies. The types of donations subject to the New Measures include funds and tangible property, though they are not necessarily exclusive. In particular, the New Measures provide detailed guidance on what donations would be considered appropriate, in part by expressly listing acceptable purposes for donations and prohibited types of donations. Additionally, the New Measures further require that health care institutions establish appropriate controls and procedures in accepting donations.

Although the New Measures technically apply to health and family planning institutions and organizations receiving donations, the detailed guidelines may indirectly impact how life sciences companies provide donations to those organizations and institutions. In turn, life sciences companies, both foreign and domestic, may want to ensure that their internal controls are consistent with the requirements of the New Measures.

Permitted and Prohibited Donations

Unlike the Old Measures, the New Measures expressly enumerate the types of donations that recipients are permitted to accept, which include donations for public health care education, training health care professionals, academic activities and research studies, discounting or waiving costs for medical treatments, and other non-profit programs. At the same time, it expressly prohibits acceptance of certain categories of donations, which include donations related to profit-seeking commercial activities, donations related to the procurement or purchase of products or services, donations where the donor has an interest in the economic benefits, intellectual property rights, research results or industry data of said donation, and donations that do not conform to laws and regulations or involve potential unfair competition and commercial bribery.

Interestingly, the prohibition against commercial bribery appears to create a link to the SAIC and local AICs. As noted above, while the New Measures apply directly to health care-related institutions, its list of expressly permitted and prohibited donations could potentially affect the AIC's interpretation in its commercial bribery enforcement actions.[1]

Procedural Requirements

The New Measures also set forth certain procedural requirements for donations, many of which are expansions of the Old Measures. For example, donations must still be documented via a written agreement, but the New Measures expressly require that certain information be specified, such as the type, quantity, quality and value of the donated items, the intention and purposes of the donation, restrictions on the management and use of the donated items, etc. The New Measures further provide clear requirements on the method of making donations, including, among other things, that monetary donations be made via bank transfers and that donations in the form of tangible property (*e.g.*, products or equipment) undergo fair market valuation, preferably by a third-party appraiser.

The New Measures also appear to take a further step in requiring transparency. A donation recipient is required to publicize its written policies on accepting donations and disclose donations it has accepted, including the nature of the donated item, the value of such item, and how the item is used, on its website or via mainstream news media. Donation recipients must also report accepted donations in its annual financial statements, along with detailed explanations. Moreover, donation recipients are required to answer public inquiries about donations that they have accepted.

Notable Provisions that Require Further Clarification

The New Measures contain two provisions that are unclear, but may have particular relevance to life sciences companies in China. The first is a requirement that donations for training health care professionals, academic activities or scientific research may not designate the specific recipient or beneficiary. It is unclear, however, whether the scope of this restriction includes company sponsorships of specific health care professions ("HCPs") to attend academic meetings or professional trainings, or sponsorship of a particular principal investigator in conducting certain medical studies or clinical trials. The second requirement is an express prohibition against donations related to "profit-seeking commercial activities," which is not further defined. It is unclear whether this provision could be interpreted broadly to preclude donors from allowing display booths, spaces or other product promotion or marketing presence at an event.

Since its announcement, there has been little public information about enforcement actions pursuant to the New Measures, so it remains to be seen how the NHFPC will interpret these provisions. Nonetheless, some local hospitals and NHFPC-regulated entities have made public announcements stating that they will update their donation policies to comply with the New Measures.[2] For the time being, however, life sciences companies should pay close attention to further guidance or enforcement signals from the NHFPC and AIC with respect to donations and grants.

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[1] As of the time of this article, the AIC has not published any cases instructive to this point and it remains unclear how the New Measures will influence AIC enforcement behavior.

[2] On January 10, 2016, Peking University People's Hospital implemented a local policy regarding administering the receipt of non-profit donations, based on the New Measures. Similarly, on February 18, 2016, Chongqing Cancer Hospital implemented a local policy regarding administering the receipt of non-profit donations, based on the New Measures. On May 10, 2016, Tianjin Health and family Planning Commission announced on its website that the local districts/counties and hospitals should follow the New Measures.

II. Compliance Controls and Monitoring in Relation to Donations and Grants

While the ultimate impact of the New Measures is yet unclear, the underlying compliance risks nonetheless warrant attention. In recent years, pharmaceutical and medical devices companies have made significant efforts to enhance compliance controls and monitoring around travel and entertainment expenses. However, donations and grants are not devoid of FCPA risks and they can present unique compliance challenges. The most significant of those risks stem from involvement of a third party, which means limited control and transparency. In response, similar controls and monitoring for third parties should be undertaken, some of which include:

- *Ensure Clear Policies and Protocols*

  While most companies' general anti-corruption and anti-bribery policies include provisions related to donations and grants, special attention to these issues may be warranted. For example, shielding involvement of sales and marketing functions from the company's internal decision-making process, particularly with respect to selecting recipients, can minimize potential *quid pro quo* considerations that may influence the decision (or the optics thereof). In fact, companies may want to limit the extent to which it designates eventual use of the donated funds or items to particular HCPs who would derive a benefit therefrom. Decisions on donations and grants often involve business considerations, and clear protocols can ensure that those decisions are subject to compliance controls.

- *Perform Due Diligence on the Recipient and Third-Party Intermediaries*

  Due diligence should focus on uncovering any governmental relationships and assessing the reputation and appropriateness of the recipient or donee. Bribery risks can arise where the donation may be deemed to indirectly benefit a government official linked to the recipient organization. For example, if due diligence uncovers that the recipient is an organization established by an influential government official whose position or office happens to be relevant to the company's business, the company may wish to balance the potential risks and/or take additional steps to assess the appropriateness of the donation and implement enhanced compliance safeguards.

  Also, recipients, such as hospitals, medical associations and charitable organizations, are not impervious to fraud and misappropriation, as exemplified in accusations against the Red Cross Society of China regarding donations to aid victims of the devastating 2008 Sichuan earthquake.[3] There may be additional reputational risks with providing donations to a recipient that is linked with improprieties and accusations of misconduct.

  Finally, employees might collude with the recipient or third-party intermediaries to engage in misconduct. Best practices would involve performing due diligence on any third-party intermediaries that are involved. Additionally, it may be worthwhile to understand the level of compliance controls employed by the intermediary to assess third-party compliance risks.

- *Ensure Appropriate Terms and Safeguards are Included in Donation, Grant, or Sponsorships Agreements*

  The New Measures already require that the written donation agreements set out detailed terms of the donation. Accordingly, compliance terms should also be included. Such terms can set forth appropriate anti-bribery representations and warranties, a covenant from the recipient that the donated funds or items will only be used in accordance with the stipulated purpose and will not be reassigned or transferred, an obligation to provide any required supporting documents and information to show how the funds are actually

[3] *See* here and here.

used, and audit rights (to the extent practicable), among other provisions. Also, it is not uncommon in China for donation or grant recipients to informally solicit suggestions from company employees on the use of funds, including any preferences on selecting HCPs who may benefit from the donation, which can increase bribery risk. Hence, companies may also wish to clearly stipulate the company's detachment and independence from the use of the funds.

- *Post-Donation Monitoring and Verifications*

  Similar to travel and entertainment expenses, securing supporting documentation and conducting follow-up verification are important steps towards detecting and deterring misappropriation and fraud in the context of donations and grants. Because third parties are involved, detailed supporting documentation and information tend to be more challenging to obtain. As noted above, companies may wish to establish controls and protocols for follow-up verifications and include contractual obligations for the recipient and/or intermediary to provide necessary supporting documentation and information in the written agreement.

Given the recent regulatory attention to donations and grants, particularly within China's heightened anti-bribery enforcement climate, compliance professionals in the life sciences sector may wish to pay particular attention to how donations and grants are being provided and enhance their compliance programs, where needed, to reduce compliance risks related to donations and grants.