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BUILDING A BETTER GOVERNMENT AFFAIRS FUNCTION IN CHINA

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New standards for the clinical and regulatory approval process of foreign drugs and treatments destined for China's massive pharmaceutical market are clouding future revenue projections for multinational drugmakers. They also represent an opportunity.

Indeed, a closer look at the regulatory challenges multinational pharmaceutical companies face in China suggests ways that forward-looking multinationals can get more value from their government affairs (GA) functions there. By employing a more sophisticated and thoughtful approach — and better understanding the talent needs that are required — multinationals can better position themselves for long-term success in China's fast-growing market for pharmaceuticals.

The lure of growth

China's pharmaceutical market has grown tremendously in the past 20 years and is now poised to overtake Japan to become the second-largest market, behind the United States, by spending on drugs and treatments.[1] For its part, Morgan Stanley estimates that Chinese pharma spending will likely double over the period between 2012 and 2017, by which time it could represent 15% of the $1.2 trillion in expected global spending on pharmaceuticals.[2]

As these numbers suggest, sales have not been an issue for drug producers, as the Chinese government continues to expand its social insurance blanket and widen the role of the private sector (for example, the country's Ministry of Health has suggested that up to 20% of hospital beds could be privatized by the end of 2015). Growth, however, has come with challenges. Margins, for instance, are lower in China than in the West. Moreover, even as Beijing has encouraged foreign drugmakers to partner with domestic peers, scandal has, at times, touched both global and domestic players and provoked a stern official response.[3]

Beyond stamping out corruption, the government has other plans for the industry — most notably, reshaping the country's domestic pharmaceutical market by redistributing expertise from foreign entrants to domestic peers, as it has done in other technology-based industries.

1 Philip Leung, Grace Shieh, and Ellon Xu, "Embracing China's brave new pharmaceutical world," Bain & Company, June 4, 2014.
2 Dimitra DeFotis, "Pharma Sales Growth in Emerging Markets Could Top 8%, Margins Need to Improve," blog, barrons.com, January 6, 2015.
3 Adam Jourdan, Kazunori Takada, and Ben Hirschler, "Bribery scandal dents Big Pharma sales in China," Reuters, September 18, 2013.

No longer content to drive Chinese GDP growth through foreign direct investment, the current administration is emphasizing China's domestic capabilities and looking to achieve a sustainable rate of growth through innovation. To that end, the government encourages partnerships between foreign and domestic drugmakers as well as with local Chinese clinical laboratories.

Moving the goalposts

For multinational pharmaceutical companies, these external factors ratchet up pressure on management, raise levels of uncertainty, and cloud profit forecasts. Meanwhile, increased government oversight raises the bar for the performance of foreign pharmaceutical firms' GA functions.

Nowhere was this on more vivid display than in early 2014, when the Chinese Food and Drug Administration (CFDA) announced that foreign drugs would henceforth require three applications and three approvals, up from two applications and two approvals. This move caught many drugmakers by surprise, and the absence of details around implementation and the grandfathering in of existing applications left some multinational corporations (MNCs) wondering whether there should have been advance notice. In retrospect, the lack of communication perhaps shouldn't have been so surprising. Apart from the government's historical reticence in such matters, it's worth noting the resource constraints involved: China's Center for Drug Evaluation (CDE), under the country's CFDA, with a staff of roughly 110 employees, regulates more than 4,000 pharma companies. By contrast, its US counterparts, The Center for Drug Evaluation and Research (CDER) and The Center for Biologics Evaluation and Research (CBER) of the US FDA, regulate about 200 pharma companies and collectively have a staff in the thousands. Moreover, the entry barriers in the United States, in the form of application fees, are much higher.

Tasked with monitoring developments in government policy and attitudes, the GA functions at many international pharmaceutical companies were in many cases the most surprised of all. After the change was announced, many GA leaders struggled to gain insight into the decision from either policymakers or other regulatory stakeholders, and some found that they lacked both the strategy and execution channels to mitigate the challenge.

While some questions regarding the policy reinterpretation remain unanswered (and likely will), the business of developing and producing drugs and treatments for Chinese patients carries on. For senior pharma executives and the GA functions that support them, the relationship with government stakeholders must improve to meet new challenges, even as they work harder to learn from the lessons of the past.

Indeed, forward-looking MNCs are starting to recognize that these events present an opportunity to reframe the way the GA function engages with stakeholders, while also preparing their organizations to successfully compete for a future in which strategies, structures, and talent are recalibrated to anticipate and engage a changing market rather than merely react to it. In our experience, organizations that professionalize their GA functions will be best placed to navigate this new environment.

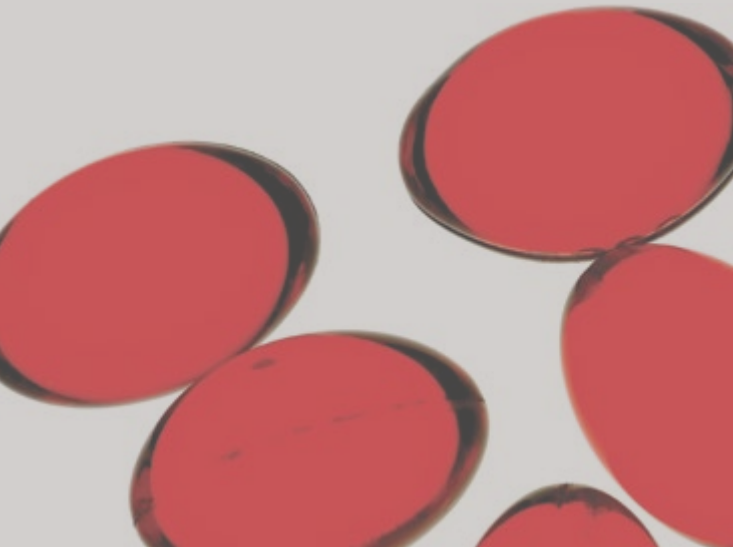
Time to collaborate

The CFDA's departure from the "two applications, two approvals" process created immediate issues for the regulatory affairs (RA) teams of multinational pharma players. While the regulatory changes might appear as an RA challenge at first, it was actually an area where GA teams could best support, coordinate, and lead the response (see sidebar "Pharma is different").

The core challenge the regulatory change highlighted is the relative lack of regulatory clarity in the industry, especially for projects currently in the approval process. Industry trade press has spilled considerable ink over the issue, but the CFDA itself has been, characteristically, quiet. Letters of inquiry were sent by most firms to the CFDA seeking clarification on the ruling; the response, however, was to acknowledge that the letters had been received and were under consideration.

Pharma is different

Often viewed as synonymous in other countries and industries, government affairs (GA) and regulatory affairs (RA) provide distinct services to pharmaceutical firms in China. GA covers the traditional roles as an external government liaison and an internal source of insights into policymaking. RA, on the other hand, is a more narrowly focused scientific function that aides in preparing for and navigating the clinical approval process of specific treatments.



In such circumstances, more nuanced channels to share messages with the regulators and the broader Chinese public might have had a material effect (and could again in the future). Quiet phone calls arranged between the local CEO and a policymaker, or meetings on the sidelines of a public event or other engagements, should be staples of GA best practice — but often aren't. The lack of visibility into the Chinese government's motivations on such a vital issue to the success of MNCs in China draws attention to the increased role the GA function can play. While more effective coordination and support for the RA function would almost certainly not have changed the policy, it might have given pharmaceutical executives an earlier opportunity to comment — or, at a minimum, prepare.

More than ever, RA professionals in China need the help of their GA colleagues. The magnitude of the shift in regulatory policy and the competitive environment necessitate greater assistance and coordination between these typically siloed departments to build and maintain successful relationships with regulators. Five steps can be taken today to improve that most vital relationship, both at the level of individual firms and as an industry.

1 Harness public relations and corporate social responsibility programs

The pharmaceutical industry in China has suffered from lackluster public relations (PR).[4] Since pharmaceutical distribution and sales practices were thrust into the spotlight, the industry has been saddled with blame for high drug and treatment prices in China. In reality, pricing is a more complex issue, involving international and domestic drugmakers, policymakers, and healthcare providers.

One way the GA function can adapt is to shift from a purely responsive organ to a proactive partner of the pharma company's corporate communications department. In addition to relaying policy considerations to executives, GA leaders should be actively working

4 Andrew Ward and Patti Waldmeir, "Big pharma fights back from China scandal," swissinfo.ch, April 3, 2014.

with the PR side of the business to inform and engage with stakeholders, including government officials, on the issues facing their company and industry. When the CFDA announced the change in approval policy, GA leaders might have resourced their PR teams with clear, tactful messaging to communicate the effects of this change on public health issues. Most did not, however, in part because corporate PR has a relatively short history in Chinese business and is not as sophisticated as it is in the West. Indeed, in the China offices of some pharmaceutical companies there is no PR function at all. Moreover, even where it is well developed, the levels of cross-functional collaboration are often poor.

To be sure, the conversation with government officials will always be primarily about listening, but corporate communications can certainly do more to share the value that multinational firms provide to the communities in which they operate. A practical example is to draw tighter links between pharmaceutical companies' corporate social responsibility (CSR) efforts and their interactions with governments. One global pharma company, for example, has been supporting the Ministry of Health in an important public health initiative by providing data and technical know-how. Such connections can only bolster the credibility of foreign firms in the minds of government officials.

Multinational GA teams can also aid their RA counterparts in managing the effects of regulatory change by tactfully presenting the views of the public and their downstream customers to government officials. To do so effectively, many pharmaceutical companies operating in China will need to get better access to providers so they might develop stronger, broader, and deeper relationships with patients. Leveraging such relationships to present the regulators with a richer picture of the effects of any policy changes on patients' lives can only improve the nature of the company's relationship with regulators. This shift to a more proactive form of GA should not be alien to most foreign firms operating in China, as the practice is common in the United States and Europe.

Smart companies address organizational disconnects head-on, recognizing that while the benefits of greater coordination between functions such as PR and GA far outstrip the effort required, the effort must be led by senior leaders within the company and supported by dedicated resources at the country level.

2 Demonstrate the policy's effects on patients

Multinational pharma companies can also benefit by reframing the discussion away from costs and toward patients and quality of care. The stated rationale for the "three applications, three approvals" change was a greater assurance about the safety of drugs and treatments introduced to the Chinese market. Focusing more clearly on this same goal could help MNCs open a broader discussion with regulators.

One of the clearest ways companies can demonstrate a new drug approval policy's effects is to support their conclusions with data, by commissioning research, for example, from a respected third-party provider. Such data could examine the clinical and commercial effects of the changes on bringing new treatments to market, for example, and include the implications for patients' access to treatment. Data should also be employed to demonstrate the economic effects on domestic drug manufacturers. High-quality empirical research of this type helps create an authoritative external reference point that government officials and management can discuss without the latter party risking the perception of being unnecessarily provocative.

Data-based advocacy could significantly improve the level of engagement with regulators and broaden the discussion. Facilitating a collaborative relationship where industry representatives and regulators explore together the economic and scientific effects of policy changes should always be the goal. Argumentative language and aggressive posturing should, of course, be eschewed at all times in favor of measured, collaborative dialogue.

Direct advocacy is also important. As the Chinese government nurtures the domestic pharma industry and looks to stamp out improper sales techniques and other forms of corruption, it may bring a natural wariness toward foreign pharmaceutical companies. Thus far, much of the resulting advocacy burden for multinational

Government affairs self-evaluation
5 questions to ask

一 PR / CSR COORDINATION

How integrated is your company's government affairs (GA) function with public relations (PR) and the organization's corporate social responsibility (CSR) activities? Would your PR and CSR functions know how to assist your GA function?

二 PUBLIC CONVERSATION

Does your firm have a compelling, concise description of the effects of the "three applications, three approvals" process? Could you easily articulate its effects on the public's access to quality healthcare?

三 DOMESTIC ALLIANCES

Who are your domestic GA partners? Would you have access to and working relationships with executives at your Chinese peers if you wanted to collaborate or discuss an issue?

四 VOICES OF INFLUENCE

Whose voices could best represent your company's interests in public and private GA discussions? Do you have respected advocates and ambassadors, both in China and internationally?

五 GLOBAL RESOURCES

When was the last time your global GA resources were deployed in China, either through personnel or research? Are your global executive leaders adequately briefed on the impact they can have on local market discussions?

pharmaceutical firms in China has been shouldered by the R&D-based Pharmaceutical Association Committee (RDPAC). Representing 40 companies, RDPAC articulates the contributions of the international firms in China, with an emphasis on its members' investment in manufacturing and research facilities. While such advocacy is necessary, it isn't sufficient and shouldn't preclude pharma companies from acting on their own behalf as well.

In fact, the way through any regulatory impasses will be for international pharmaceutical firms to be more, not less, directly involved in communications with the government. Effective representation through in-house GA leaders must acknowledge underlying Chinese cultural assumptions that guide interactions with government leaders — whether by individuals, a company, or an industry body. Operating on cultural principles imported from other markets is shortsighted and will inhibit constructive dialogue.

For example, drugmakers' interactions with regulators in China are very different from the ones they have in the United States. The difference in accessing Western versus Chinese officials can be thought of using the analogy of an avocado and an egg. Just as the avocado has a soft exterior and hard core, Western regulatory officials readily grant personal access but are typically unwilling to grant access to core decision-making processes. Chinese officials, for their part, resemble the egg. Although they present a hard, seamless shell, they are more fluid underneath. While initially slow to grant access, Chinese decision makers may invite trusted counselors to share their opinions.

3 Build alliances with domestic drugmakers

Improving the relationship with government officials, including regulators, must be a core focus of a strengthened GA function. However, it is not the only way forward. Just as regulators are likely to respond positively to economic and scientific research, they are also likely to look favorably on positive feedback from the domestic pharmaceutical industry. Given China's stated goal of developing local Chinese players, cultivating relationships with domestic management is a prudent course for multinationals to take. There is substantial scope for inviting domestic Chinese drugmakers to contribute their influence and understanding to their foreign GA peers.

For example, many of the senior executives and board members of Chinese pharmaceutical firms also serve on committees of the Chinese People's Political Consultative Conference and National People's Congress, two of the country's highest political bodies. Participation in these bodies grants access to policymaking at a level that foreign GA leaders and their executives cannot reach on their own.

Relationships with domestic peers will give foreign GA leaders relational, albeit indirect, access to policymakers. Even if meetings with government regulators cannot be arranged, the management at domestic pharmaceutical firms can offer vital insights into the prevailing regulatory mind-set. While MNCs should pursue only alliances and joint ventures with a clear strategic rationale behind them, they shouldn't overlook the opportunities that such tie-ups afford them when it comes to amplifying their messages with regulators.

4 Cultivate additional voices of influence

Balancing broad, public discussion and engagement with experienced retired senior government officials can also help cultivate valuable influence for multinational firms in China. While RDPAC has successfully pursued the bottom-up approach of engaging with the public, more can be done to build strategic connections with key opinion leaders, especially the growing number of retired policymakers.

Too often the conversation between foreign drugmakers and regulators is adversarial. Rather than frame the discussion as between two competing positions, influential figures in China's public health dialogue can help bridge the two sides. GA leaders should actively identify and resource these key influencers using trustworthy economic and scientific research, as discussed earlier.

Government officials can be invited to engage with foreign pharmaceutical companies' internal events. When firms hold their annual staff gatherings, for example, the insights and perspectives of experienced officials would hold great value for RA staff, while potentially deepening essential rapport between GA leaders and local officials.

Within the Chinese government's oversight of the pharmaceutical industry, much can also be done to cultivate support in new quarters. Drug regulation is split among China's Ministry of Health, the CFDA, the National Development and Reform Commission (NDRC), and the Ministry of Human Resources and Social Security. At the local level, drugmakers are confronted with similar layers of bureaucracy as they navigate import procedures and regulations, taxation, tendering processes, and labor relations.

GA leaders in foreign pharmaceutical companies should rigorously examine their levels of access and networks beyond routine regulatory oversight. While the first generation of GA leaders in China were more likely to possess such connections, today's GA leaders must now apply themselves to improve this core responsibility.

5 Bring global leadership and policy experience to China

Managing relationships with a wider array of current and retired government officials requires a thoughtful, coordinated GA strategy. Foreign pharmaceutical firms attempting to improve influence and access without bringing the full resources of a global organization to bear are unnecessarily limiting their efforts.

Much of the GA work done in China by MNCs has been driven locally, however, and companies' failure to tap into the experience and insight available in a multinational firm has hindered support for their efforts. Global leadership at multinational pharmaceutical firms needs to better understand and more actively support the efforts of local GA and RA functions.

Companies can start by making better use of global executives' time spent in China. Many of the biggest global drugmakers send their CEOs to international economic forums in China, yet far too many hop back on the plane without meeting national, or even local, government officials.

Direct engagement with Chinese officials and influencers is the natural starting point, but much can be done outside of China too. Numerous exchange programs between Chinese and American government agencies, as well as European pharmaceutical agencies, offer invaluable opportunities to share new opinions about regulatory issues with Chinese officials and patiently seed future discussions.

Much of this can be done through global trade organizations, such as the Pharmaceutical Research and Manufacturers of America (PhRMA). Representing the interests of the largest American drugmakers, PhRMA could more seamlessly convey the concerns and proposals of multinational drug companies in China as a part of the group's existing market education efforts.

Hire the whole package

At its most simple, GA is about business planning and access to government. The simple view, however, is no longer sufficient for orienting government affairs in China. Multinational pharmaceutical companies have run sizable GA functions for decades, but the experience levels and skills of the teams have changed.

In the past, the heads of GA were often leaders with impeccable access to the highest levels of policymaking because of shared connections among the first generation of leaders thrust into positions of responsibility when China opened up. The small leadership pool of the late 1980s and early 1990s meant interconnectedness was almost assumed among the governmental authorities and corporate executives. Many GA leaders from that first generation have since moved on to other pursuits, opening the way for a new generation. This new cohort, however, does not generally have the same level of intrinsic access to government officials as its predecessors did, in part because industry growth and the rise of domestic players mean that multinational

What makes an effective government affairs leader in China?

PERSONAL CHARACTERISTICS & ATTRIBUTES

Integrity
Unquestionable personal integrity and moral compass.

Access
Strong ability in accessing or communicating with senior-level government officials through either personal or professional networks.

Adaptability
High emotional and cultural IQ; able to relate to, and work with, "both sides of the aisle."

Communication
Inspirational and effective communicator.

Maturity
Respected senior leader with stature within the professional community.

LEADERSHIP SKILLS

Strong mentality to "support" business growth with creativity, energy, and passion.

Proven leadership skills or style in utilizing and motivating a sizable professional cohort at both central and provincial or local levels.

Ability to communicate plans with various stakeholders, both internal and external, effectively.

Ability to carry out plans through effective leadership, as an individual contributor or by leading a team.

INDUSTRY OR SECTOR KNOWLEDGE

Strong industry expertise, in this case the pharmaceutical and medical device industry.

In-depth understanding of the structure, practices, and standard policies of governing bodies in China.

Ability to understand and leverage PR and CSR effectively.

Ability to demonstrate policy's effects on patients.

Skill in building alliances with domestic drugmakers.

Ability to bring global leadership and policy experience to China.

pharma companies contribute relatively less to the overall employment and industry investment as they once did and are therefore no longer "valued" as much. To compensate, the accompanying skills of the GA team leader must be that much sharper (see sidebar "What makes an effective government affairs leader in China?").

Within global, multifaceted pharma organizations, for example, leadership integrity is especially valued in GA team leaders. Recent public relations crises around pricing and physician subsidies saw the integrity of some firms' GA teams exposed. Substantive business skills and access are vital for GA function heads, but personal integrity must be the starting point — and must be maintained above all.

Intelligently allocating resources within the GA function is another vital skill that GA leaders should possess. Establishing responsible, sustainable structures that address the needs of such a broad group of stakeholders (including government officials and internal company stakeholders) requires exceptional managerial skills. Running an expanded, energized GA function, and actively coordinating with PR and RA counterparts, calls for effective team-building and personnel-management skills.

A high-functioning GA leader should also be a strong collaborator, able to effortlessly communicate and coordinate activities and plans with both global and local stakeholders and thus earn buy-in for future efforts.

A new opportunity

The dynamic and occasionally unpredictable environment that characterizes China's pharmaceutical industry calls for new levels of coordination, leadership, advocacy, and creativity from multinational firms' GA leaders. More than ever, the GA function has an opportunity to make significant contributions to its colleagues and the industry at large. Realizing the opportunity will require GA leaders to coordinate with public relations and corporate social responsibility programs, demonstrate the effects of policy changes, build alliances with domestic drugmakers, cultivate relationships with key opinion leaders, and better leverage their firms' own pools of global leadership.

Understanding the ramifications of the "three applications, three approvals" testing process and adjusting business plans accordingly has been a top priority for foreign drugmakers in China since mid-2014, and it will remain an area of focus for 2015. Smart companies are looking even further ahead, grounded as they are in the insight that future business projections rest on better understanding, and resolving, these fundamental regulatory questions through the efforts of a much strengthened GA function. Such efforts can help the pharmaceutical industry find solutions that meet the needs of both multinational companies and concerned local governments. Companies that invest in building strong GA functions will have the upper hand in navigating the fast-changing market for pharma in China and can position themselves well for years to come. ■

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Healthcare & Life Sciences Practice

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