FEATURE

Agile responses to China’s health care transformation

Launching innovative biopharma in China

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In this final article of a four-part series, Deloitte writes a reality check regarding China’s shape-shifting health care environment. Are you as agile as you could be for your next launch to excel?

The media rarely allows us to forget the trade wars taking place between the US and China, and biopharma companies looking to launch innovative products in China are, no doubt, anxiously monitoring that situation. But what may be escaping your attention are the less overt tremors rippling throughout the industry, which should matter just as much – if not more: China’s deepening health care reform with a growing tiered system, the many budding innovative Chinese newcomers (as of 2018, more than 130 Class I domestic pipeline products were registering or in Phase 3), and changing payers at the subregional and hospital levels, as well as in the private sector.

Having just one area of uncertainty could easily affect all aspects of a biopharma company, not to mention a specific product launch strategy, in China. As depicted in Figure 1, the changes are rapid and transformational, and they bring challenges. Biopharma companies need to establish a system that comprises agile methods and a China-centric perspective, to keep afloat on the sea of change, but also to succeed.

In Deloitte’s experience, many multinational companies have not yet established an internal structure or systematic launch framework that permits an agile approach to China. They apply a generalised planning approach and key performance index, then encounter difficulties when unexpected market events take place. For a successful launch of an innovative product in China, most biopharma companies need to make the four big changes shown in Figure 2.

Many companies may think they are meeting the challenges China is throwing at the industry, but they may not be acknowledging the common problems outlined below. There are a lot of ways to build resilience, and help turn what could be a perfectly adequate product launch into a winning one.
FIGURE 1
Major recent health care reform events in China (non-exhaustive)

Key policies across timeline

2015
- 2015.8 Reform of drug and medical device approval regulation
- 2016.2 Policy on prioritizing approval to address backlog of drug registration applications and set up priority review
- 2016.3 Policy on generic drug consistency evaluation

2016
- 2015.6 Announcement on instructions for improving public hospital centralized procurement
- 2016.5 Announcement on advancement of central procurement for negotiation product
- 2016.6 Pilot scheme of Marketing Authorization Holder system for drugs

2017
- 2017.2 Policy on reform and improve policy on drug manufacturing, distribution and using process
- 2017.3 New National Reimbursement Drug List (NRDL) updates and 44 products entering negotiations
- 2017.10 Opinion on Strengthening the Reform and Approval Process to Encourage Drug and Medical Device Innovation
- 2017.12 Standard for generic products

2018
- 2018.3 CFDA reformed and renamed as National Medical Products Administration (NMPA)
- 2018.7 Guideline for Acceptance of Overseas Clinical Data and implementing a 60-day review period for clinical trial applications
- 2018.9 Another 17 oncology products agreed discounts to gain national reimbursement
- 2018.10 Update of the essential drug list (EDL), including the addition of 12 oncology drugs and 22 urgent clinical drugs for children
- 2018.11 Trial of 7+4 centralized procurement in major 11 cities including Beijing, Tianjin, Chongqing
- 2019.01 Announcement of new round of negotiation and a dynamic update of NRDL, e.g., to add oncology drugs and to trade volume for price
- 2019.03 Increase reimbursement of major and critical disease from 50% to 60%
- 2019.03 Announcement of a list of 30 drugs, already approved overseas, that identified as urgently needed in the clinical set. This is the second batch after 2018

2019
- 2019.01 Announcement of new round of negotiation and a dynamic update of NRDL, e.g., to add oncology drugs and to trade volume for price
- 2019.03 Increase reimbursement of major and critical disease from 50% to 60%
- 2019.03 Announcement of a list of 30 drugs, already approved overseas, that identified as urgently needed in the clinical set. This is the second batch after 2018

2020
- 2020.01 Announcement of new round of negotiation and a dynamic update of NRDL, e.g., to add oncology drugs and to trade volume for price
- 2020.03 Increase reimbursement of major and critical disease from 50% to 60%
- 2020.03 Announcement of a list of 30 drugs, already approved overseas, that identified as urgently needed in the clinical set. This is the second batch after 2018

1. **Manage uncertainties efficiently**

**Typical problem:** There are too many uncertainties and your launch team struggles to plan around the full range of them. By expending so much energy trying to identify all the potential risks and future scenarios you cannot form the ability to make good decisions in the face of uncertainty.

**Solutions:**
- Senior leaders need to understand the overall industry trends for the business, but become especially familiar with general policy direction, rather than creating detailed plans for individual changes or policy updates. Being able to grasp where the market is heading, and using it to guide an efficient, overarching launch strategy, is critical.
- Global and local product launch teams should work closely together to build a scenario-based framework. Good scenarios challenge the key assumptions that underpin the baseline view, allowing you to peer around the corner at alternative versions of the future. You should:
  - prioritise uncertainties based on probability and impact
  - feed them into various scenarios and pilot simulation exercises
  - analyse the scenarios, including their impact on brand performance
  - practise flexibility in considering the various outcomes, and make necessary adjustments accordingly.
2. Empower internal teams

**Typical problem:** Organisational bureaucracy in decision making is preventing your products from achieving the ideal launch. A restrictive hierarchy can happen at the global/country level, or within China, or even among various teams. What's more, outdated company processes are burdened with legacy thinking and systems. All these factors contribute to poor timing of decisions and reactions to the changing market space.

**Solutions:**
- Establish dedicated functions or 'SWAT' teams with more resources and ownership of ultimate decisions. With a flexible structure and agile way of working, they can respond to changes and explore bold or new product launch ideas in China’s dynamic health care environment.
- Build a quick course-correction mechanism. With historically limited real-life insights, and an inflexible commercial model, it can be impossible to monitor performance dynamically and make course corrections. Establish a way to minimise risk while you embrace uncertainty – that way, if you fail, you can fail fast and then change tack.
- Implement flexible key performance indicators (KPIs) for the ‘SWAT’ teams, as well as other functions, such as finance and compliance. This will unlock value by allowing teams to pivot around disadvantageous situations, or be more malleable in product launches and enable quick reactions to business needs.

3. Build a rapid decision and learning cycle

**Typical problem:** Your launch activities in China are repeatedly hampered by a fixed planning cycle (annual/quarterly), whose timing is not in line with significant market events. This rigidity leads to conflicts between global and country teams when it comes to overall KPIs and planning.

**Solutions:**
- Align the strategies of global and local teams with each other early on, ensuring they are allowed flexible collaboration to make the smartest choices for a specific launch. And remember that a culture shift is required for non-Chinese teams to work with any Chinese team.
- Establish a mechanism that allows in-country feedback and adjustments to deal with unexpected product launch outcomes. For example, any significant local insights collected by the sales team would reach your branding lead efficiently. Give local teams clear responsibility and authority, and encourage more autonomy in staff.
4. Explore external partnerships

**Typical problem:** Your organisation responds slowly to changes because there is not sufficient capability to deal with everything in the product launch process. But you are wary of building partnerships, seeing them as transactional and carrying risks.

**Solutions:**
- Build your agility by entering partnerships that can enhance your capabilities in terms of data and service. Many Chinese vendors/partners can offer an in-depth understanding of the local markets, expertise in a special field and their own resources and channels to go to market. Take, for example, Ali Health: a subsidiary of the tech giant Alibaba Group that has strong technology capabilities and wide customer reach. Recently, a big biopharma company partnered with Ali Health to take advantage of these capabilities, delivering new smart health services that aim to help patients find and stay on the right medicines. By reaping a partner’s benefits, you can engage in outcomes-based contracting, better understand how therapies are used and improve patient outcomes.
- Work around the tightening restrictions on your sales team by embracing alternatives. Those companies that have invested in digital partnerships have found value in them already, given the limitations being placed on sales representatives.
- Foster dynamic partnerships through strategic alignment of both parties, a close working culture, good communication between internal and external stakeholders, and a dedicated project team that can have some autonomy and agility to ensure successful execution.

**FIGURE 3**

**Examples of partnerships that allow for cultural adaption, local market understanding and improved patient outcome**

- **Collaboration with commercial payers**
  - Cooperate with private insurers to develop innovative payment models, such as payment for outcomes

- **Application of technology by digital companies**
  - Leverage wearable device and digital platforms to access patients and track launch outcome

- **Innovation in physician education model**
  - Improve physicians’ loyalty and activity to reach, communicate and educate effectively

- **Innovation in go-to-market models**
  - Effectively reach lower-tier physicians through co-promotion or purchase of service

- **Partnerships with government agencies**
  - Win government support and use administrative power to organise programmes/campaigns

Conclusion

Being aware of the rapid-fire changes shaking up China’s health care environment is simply not enough these days. The changes demand that bio-pharma companies look hard at their approach to uncertainties, team empowerment, adroit decision making and smart collaboration with partners. The successful product launch is one that reflects agility at a programme and enterprise level, and the bonus is the introduction – or reintroduction – of speed, flexibility, customer focus and continuous improvement to the core of your company.

Explore further insights into launching innovative biopharmaceuticals in China with three other articles in this series, on: market access and reimbursement, digital technologies and regulations.
Endnotes


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