ALLEN & OVERY

GENERIC CONSISTENCY EVALUATION IN CHINA: THE COMING PARADIGM SHIFT IN DRUG PRICING AND PATENT CLIFF

China is one of the largest generic drug markets in the world. As part of the drug approval reform, the ongoing generic consistency evaluation (**GCE**) is likely to have significant, long-lasting impacts on the market landscape, drug pricing and generic competition. Patent cliff might inevitably follow and should be examined and planned for early.

INDUSTRY-WIDE GENERIC CONSISTENCY EVALUATION IS UNDERWAY

On March 5, 2016 the State Council General Office issued the Opinion on Conducting Consistency Evaluations of the Quality and Efficacy of Generic Drugs ("Opinion"). Signalling a push for an industry-wide overhaul of generic drug quality, the Opinion sets forth the new evaluation and approval requirements for generic drugs that have been approved for marketing, including both domestic and imported generic drugs. During the past year, the China Food and Drug Administration (CFDA) has issued various guidelines and notices concerning the GCE process.

Historically, there is no mandatory bioequivalence study as part of the generic approval process in China. Generic drugs are not required to undergo bioequivalence testing against branded drugs. Instead, generic drugs only need to show conformity with the so-called "national standard". Therefore, generic drugs are not deemed "equivalent" to branded drugs.

The current GCE campaign is retroactive. Under the proposed timeframe, oral solid dosage drugs on the national Essential Drug List approved for marketing before October 1, 2007 should have completed the evaluation by the end of 2018. For drugs that need to undergo clinical trials for efficacy testing, the deadline for completing the conformity assessment is the end of 2021. **Importantly, failure to timely pass the GCE will lead to the revocation of registration licences or ineligibility for government tendering**. To incentivise the generic pharmaceutical companies to carry out their in-house GCE, the Opinion stated that for each tendered drug, no more than three drugs would be allowed to pass the GCE. In this sense, the GCE process becomes a race among the generic pharmaceutical companies in China.

Further, the Opinion sets forth the requirement for reference products, compared to which the GCE should be conducted. According to the Opinion, a reference product must be the branded version of a generic drug or an internationally acknowledged generic version, if the branded version is unavailable. In a recent State Council's press conference, the CFDA's director noted that the office responsible for the GCE has received over 4,000 reference product listing applications in respect of over 700 drugs.

WHAT ARE THE LIKELY IMPACTS?

The GCE, first and foremost, is a quality initiative. In its official explanatory document, CFDA describes the GCE as crucial to "remedying the past" so as to fill in the quality gap between generic drugs and branded drugs.

In addition to improving the quality of generic drugs, the GCE is also expected to influence drug pricing, and consequently lower the cost of medical care, in China. Even though there is no clear guidance from the government at this point on the pricing of generic products passing the GCE, most people believe that they will directly compete with off-patent drugs during the tendering process, without the current protection of "patented" status for the latter. See our previous article on drug tendering in China here.

In essence, given the improved generic quality brought by the GCE, it likely leaves no justification for allowing premium pricing for off-patent branded drugs. Undoubtedly, this would mean more fierce competition between off-patent originators and local generic companies.

From a policy perspective, the GCE is part of greater regulatory efforts to foster the pharmaceutical sector in China. Currently, there are more than 6,000 pharmaceutical companies in China. Given that a substantial number of local companies may lose licences or fail to qualify for tenders, one further consequence of the GCE is the likely consolidation in the sector.

IP IMPLICATIONS: PATENT CLIFF

A GCE-compliant generic drug will create an equivalent of patent cliff. While an originator's revenue could "fall off a cliff" after the patent expiry in most international markets, we have not seen real patent cliff in China in terms of price erosion or loss of market shares. The reason for this is that the off-patent branded drugs have been shielded from direct generic competition in the hospital market. Specifically, most of these drugs currently receive the "improved quality score" based on their expired patents in tendering. Such preferential treatment is likely to be eliminated after the GCE is completed within the next three to five years.

As a result, the GCE will bring about an entire new set of issues relating to dealing with patent cliff in China. Now is perhaps the right time to start reviewing the patent strategy for the existing product portfolio. In particular, after the primary patent expires, the secondary patents will become the main deterrence and enforcement of these should be examined and planned for early.

Validity challenge

For a product with effective primary patent protection, the GCE creates an additional incentive for generics to challenge the validity of the primary patent to start early generic competition. In the pre-GCE era, the lack of direct competition somewhat discourages generics from entering into the market early. Aggressive generic entry may also be prompted by the government policy indicating that only up to three GCE-compliant generic drugs will be approved in future.

Settlement strategy

With the anticipated increase in validity challenges, MNC pharmaceutical companies not only need to prepare early to defend their patent portfolio, but should also consider possible settlement strategy, if it becomes a necessary step.

Strategic arrangement

For a product with expired or expiring patent(s), a company may consider capturing a portion of the generic market by launching its own authorised generic version. Note that the Chinese regulatory and pricing regime will not allow a company to hold two separate licences for the same product, thus making it impossible to sell the same product under two different brands. Consequently, the authorised generics may have to be arranged through a strategic partner.

Adding to the challenge of devising commercially sound patent and product life-cycle management strategies, any change will take place in the context of ever-increasing scrutiny of the pharmaceutical industry by the Chinese competition agencies. Extreme care will be required in order to minimise antitrust exposure when bringing up an authorised generic drug with a partner or settling patent litigation with potential competitors.

Contact

David Shen
Head of IP - China
Tel +44 20 3088 3255
Mob +44 7827 883429
david.shen@allenovery.com

Jill Ge
Associate - Litigation
Tel +86 21 2036 7124
Mob +86 1391 7896 688
jill.ge@allenovery.com