

LOWER BAR FOR MERGER SCRUTINY?

FIRST BELOW-THRESHOLD DEAL CLEARED WITH CONDITIONS IN CHINA

Competition authorities are increasingly finding ways to review transactions that fall below turnover thresholds and China is no exception. In September, details emerged of a transaction in the Chinese pharmaceutical sector, whereby a below-threshold acquisition underwent an extensive review process involving the Chinese competition authority's "stop-the-clock" powers. The review resulted in a conditional clearance decision involving remedies that were both structural and behavioural. In this article, we take a closer look at this unusual decision and highlight key takeaways from the case.

Simcere/Tobishi - acquisition of a downstream rival by an integrated supplier/manufacturer

On 22 September 2023, the Chinese competition authority, the State Administration for Market Regulation (**SAMR**), conditionally cleared the proposed acquisition by Simcere Pharmaceutical (**Simcere**) of a batroxobin injections manufacturer, Beijing Tobishi Pharmaceutical (**Tobishi**) (referred to as the **Transaction** below). This decision is notable because the case did not meet China's merger notification thresholds. In addition, it is the first instance where SAMR has imposed conditions on a below-threshold deal.

Batroxobin is an enzyme derived from snake venom. It is used to produce batroxobin concentrate active pharmaceutical ingredient (**batroxobin API**) that can reduce fibrinogen levels in blood and treat hearing loss. Simcere had become the sole supplier of batroxobin API in China after entering into an exclusive agreement in April 2019 with the world's only producer of batroxobin API raw materials, DSM Nutritional Products (**DSM**). In 2021, SAMR fined Simcere RMB 100m for abusing its dominant position by refusing to supply batroxobin API to Tobishi, which hindered Tobishi's ability to manufacture batroxobin injections.

Before the Transaction, Tobishi was the only manufacturer of batroxobin injections in China. Simcere had been engaged in research and development (**R&D**) activities to establish its own batroxobin injections business. As such, the Transaction involved a horizontal overlap between the parties and issues around potential entry.

SAMR was concerned that the Transaction may eliminate potential entry in the market for batroxobin injections in China and consolidate Tobishi's dominant position in the upstream market for batroxobin API. Mirroring its 2021 abuse of dominance decision, SAMR also noted concerns that the merged entity may refuse to supply batroxobin API to potential downstream competitors and concluded that the Transaction may exclude or restrict competition in the market for batroxobin injections in China.

To address these issues, SAMR approved the Transaction subject to a number of behavioural conditions for at least six years, together with a structural remedy to eliminate the downstream horizontal overlap in the manufacture of batroxobin injections. The conditions included:

- Simcere must remove the exclusivity obligation in the agreement with DSM regarding the supply of batroxobin API raw materials in China;
- Simcere will divest the batroxobin injections business it has been developing;
- post-Transaction, the end user price of batroxobin injections must be reduced by at least 20% of the current online procurement price;
- post-Transaction, the merged entity must supply sufficient batroxobin injections to meet clinical demand; and
- if the exclusivity agreement with DSM has not been terminated, the divestment has not been completed or the buyer fails to conduct research and development within the required timeframe, the end user price of clinically used batroxobin injections must be reduced by at least 50% of current online procurement prices.

Key takeaways

This Transaction is a useful case study that demonstrates how SAMR is putting some of the changes it made to the Anti-Monopoly Law in August 2022 (the **Amended AML**) into action and casts light on potential enforcement trends to look out for in the future:

- (1) **SAMR's power to review below-threshold deals:** While SAMR and its predecessor, the Ministry of Commerce, occasionally have reviewed below-threshold deals in the past, this power was very seldom used in practice. The Amended AML last year highlighted SAMR can intervene in such cases if competition issues are present. By scrutinising the Transaction, SAMR signalled it will exercise this power going forward in the appropriate cases. Businesses should therefore be aware that even if a deal falls below the turnover thresholds, the possibility that SAMR may review it is now greater than it used to be.
- (2) **Ramifications of past abuse on future deals:** SAMR is likely to have had in mind Simcere's past conduct relating to batroxobin API supplies when Tobishi was a competitor. SAMR closely scrutinised this Transaction to ensure Simcere could not abuse its dominance in upstream markets to entrench its market position. SAMR's review of this Transaction suggests that companies with prior compliance failings may be on SAMR's "radar" and the extent of the conditional approval for this Transaction suggests SAMR may take a tough stance on remedies when evaluating transactions involving such companies.
- (3) **"Stop-the-clock" powers now commonly used, particularly for remedy discussions:** The Amended AML grants SAMR the power to suspend the review period under certain circumstances. In the present case, SAMR stopped the clock for 5 months during the review to allow time for multiple rounds of remedy negotiations and only resumed its formal review one day before issuing its conditional clearance. In doing so, SAMR demonstrated the flexibility afforded by its "stop-the-clock" power. While this ability to pause review timelines allow for in-depth remedy discussions without the need to "pull-and-refile", it also adds an element of unpredictability, making it more difficult for parties to anticipate how long SAMR's review will take. For this transaction, SAMR's review took in total nearly 15 months from the initial notification and conditional clearance decision. Companies expecting to discuss remedies with SAMR should therefore budget adequate time to do so.
- (4) **Innovation may influence competitive effects analysis and shape remedies:** SAMR's decision considered the Transaction's implications on the parties' R&D potential in this specialised API market and put considerable emphasis on dynamic harms beyond short-term pricing. As such, SAMR considered both behavioural and structural remedies to be necessary to address future foreclosure risks, including requiring Simcere to eliminate the horizontal overlap in the downstream market and facilitate competition. When reviewing a transaction in an innovative sector (particularly those with rapid technological developments), it is clear that SAMR (similar to its global counterparts) takes into consideration the impact on future competition through technology or product development.
- (5) **Ongoing scrutiny of the Chinese pharma sector:** SAMR's conditional approval of the below-threshold Transaction with extensive remedies underscores its intensifying enforcement focus on the pharmaceutical industry. The pharmaceutical sector has been highlighted as a priority with expected increased antitrust enforcement activity in the Anti-Monopoly Commission of the State Council's API Antitrust Guidelines (国务院反垄断委员会关于原料药领域的反垄断指南) in November 2021, Fourteenth Five-Year Modernisation of Market Regulation Plan ("十四五"市场监管现代化规划) and Fourteenth Five Year Pharmaceutical Industry Plan ("十四五"医药工业发展规划) published in January 2022. This has resulted in a flurry of antitrust enforcement activity in the sector recently: SAMR and its provincial branches have imposed antitrust fines on a number of pharmaceutical companies earlier this year (e.g. Tianjin Jinyao in March; Grand Pharmaceutical and Wuhan Healthcare in May). SAMR also held an anti-monopoly administrative guidance meeting for the pharmaceutical sector in June 2023. Pharmaceutical companies can expect SAMR to maintain rigorous oversight in future transactions that may impact competition in this important sector.

Implications for future China transactions

This conditional approval of a below-threshold transaction raises several themes for consideration regarding SAMR's evolving approach. By reviewing and imposing remedies on a below-threshold transaction for the first time, SAMR demonstrated a willingness to assert oversight beyond the usual jurisdictional thresholds. The focus on deal-specific competitive dynamics and potential to foreclose rivals (reflecting past conduct) is reflected in the remedies required for clearance. SAMR's use of its "stop-the-clock" power also illustrates the unpredictability in China review timelines.

Going forward, it may be prudent for businesses to anticipate both potential increased scrutiny of below-threshold transactions, as well as SAMR's willingness to thoroughly review deals involving complex economic circumstances. Early competition assessments and maintaining adaptability will continue to be key to regulatory planning for future M&A transactions.

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