

Antimonopoly Guidelines

For the Pharmaceutical sector

China – State Council Antimonopoly and Anti-unfair competition Committee

Main information

Scope of Application:

Definition of monopolistic behaviors in Pharmaceutical sector, applicable to implement and interpret the provisions of Antimonopoly Law, the Provisions on Prohibiting Monopoly Agreements, and related liabilities

Effective Date:

January 23rd, 2025

Related Provisions:

- Anti Monopoly Law
- Anti Unfair Competition Law
- Provisions on Prohibiting Monopoly Agreements (2023, effective: 2025, draft for comments)

Pharm.east.

Key Topics

Framework

- Further specification of "Guidelines of the Antimonopoly Commission of the State Council on the Definition of Relevant Markets", applied to Pharmaceutical sector
- Close connection with BMI funds administration, to keep lower prices and spread competition.
- Simultaneous revision of the Provisions on Prohibiting Monopoly Agreements (2025, draft for comments) to specify the conditions of Safe Harbor

What's new

- Relevant Product Market defined based mainly on **demand-side substitutability analysis**, by considering among others: intended use; therapeutic effect; price; preferences by physicians or patients; regulatory and reimbursement policies.
- Specification on what evidence the companies must provide to prove the lack of anti-competitive effects on their agreements – no impact on: drug prices, drug supply, no shortage, no delay in market access for generic drugs (**Safe Harbor Rule**)

Sensitive Factors

- Substitutability criteria are **different than analysis conducted in Centralized procurement tenders to put in competition different products** (Volume-Based Procurement): in VPB the scope of comparative analysis is give priority to selected drugs, which can lead to an evaluation of “not-eligible for substitution” or “partially substitution” in procurement, even though the same products are within the same **Relevant Product Market for antimonopoly purpose**
- Even though a certain agreement or behavior does not have antimonopoly effect, it could be interpreted as **unfair** according to Anti-unfair competition rules

Drivers

- **Relevant market analysis:** as a prerequisite for monopolistic agreements and/or behaviors, companies are advised to consider in advance whether a certain agreement or behavior can fall into a monopoly agreement or behavior by assessing the relevant market conditions and the impact on competition, prices, and drugs supply chain
- **Safe Harbor Rule:** currently under revisions for all sectors by State Administration of Market Regulations. A proposal to define with numeric criteria is currently pending at SAMR. Where approved, it will be applicable to pharmaceutical sector.
- **Burden of Proof:** Company must furnish the proof that a certain agreement falling into the conditions of monopolistic agreement does not have restrictive effects.



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