China Proposes New Rules to Address Perceived Anti-Competitive Practices in the Pharmaceutical Industry

AntitrustConnect Blog
August 18, 2017

Adrian Emch, Hogan Lovells

Please refer tot his post as: Adrian Emch, Hogan Lovells, 'China Proposes New Rules to Address Perceived Anti-Competitive Practices in the Pharmaceutical Industry', AntitrustConnect Blog, August 18 2017, http://antitrustconnect.com/2017/08/18/china-proposes-new-rules-to-address-perceived-anti-competitive-practices-in-the-pharmaceutical-industry/

On 14 August 2017, the National Development and Reform Commission ("**NDRC**") released a draft of the Guidelines on Pricing Conduct by Business Operators for Drugs in Shortage and Active Pharmaceutical Ingredients ("**Draft Guidelines**"). NDRC is seeking comments on the Draft Guidelines until mid-September.

One day later, NDRC made public the full text of its decisions against two local companies for excessive pricing and refusal to supply active pharmaceutical ingredients (see here and here), confirming its determination to use antitrust as a key enforcement tool in the pharmaceutical industry.

Background

The Draft Guidelines are a set of rules implementing the Anti-Monopoly Law ("**AML**") and the Price Law in the pharmaceuticals field. This normative effort comes against the background of the landmark drug pricing reform, on which China embarked since June 2015. Already during the launch of the reform, NDRC publicly announced it would resort to antitrust rules to ensure that drug pricing does not get out of hands.

During the months that followed, both NDRC and another antitrust authority in China – the State Administration for Industry and Commerce ("**SAIC**") – brought a number of

cases against pharmaceutical companies (see for example here and here). In its six-month nationwide campaign launched in June 2016, NDRC already listed active pharmaceutical ingredients as one of the key enforcement targets. Perhaps the release of the Draft Guidelines is a recognition by NDRC that, in its view, more needs to be done to keep drug prices in check after the pricing liberalization.

The Draft Guidelines state that their legal bases are the AML, the Price Law and other relevant rules. Interestingly, however, they do not explicitly mention the drug pricing reform from June 2015 as background.

Overview of the Draft Guidelines

The Draft Guidelines contain 19 provisions which – with broad strokes – can be categorized into four types: general provisions; rules on restrictive agreements; abuse of dominance provisions; and unilateral pricing conduct rules.

In terms of substantive prohibitions, the Draft Guidelines contain a provision each on horizontal agreements (basically, cartel conduct) and vertical agreements (resale price maintenance).

Perhaps more importantly, the Draft Guidelines contain some more or less detailed guidance on abuse of dominance prohibitions: excessive (that is, unfairly high or low) pricing; exclusive dealing; indirect refusal to deal by way of excessive pricing demands; restrictive dealing by way of discounts or similar conduct; imposition of unreasonable conditions; and discriminatory treatment.

The above-mentioned types of provisions implement the AML. Four additional provisions are aimed at implementing the Price Law and its subordinate rules. These provisions appear to sanction unilateral pricing conduct by pharma companies, with or without a dominant position: fabrication of information to drive up prices; hoarding; collusion and price manipulation; and fraudulent conduct vis-à-vis consumers.

The impact of the Draft Guidelines is potentially far-reaching – both in and outside the pharmaceutical sector.

Impact in the pharmaceutical sector

The Draft Guidelines define their scope of application broadly. "Drugs in shortage" are defined, ambiguously, as "drugs which cannot be supplied normally in a specific territory." Yet the Draft Guidelines do not explain what "normal supply" (or the absence thereof) would be. Hence, the imprecise definition may lead to much uncertainty among pharma companies, as the threat of NDRC finding unusual supply

patterns may always loom in the background.

In turn, “active pharmaceutical ingredients” are defined as “chemical or natural ingredients used to manufacture drug preparations.” Here the issue lies not so much in the imprecision of the definition, but in its breadth. The Draft Guidelines’ definition appears to go beyond the narrow notion of active pharmaceutical ingredients (as for example used by the World Health Organization), seemingly covering any kind of input materials used in a drug, even if not essential to its function. As a result, many chemicals manufacturers supplying to pharma companies may be impacted.

In short, the scope of the Draft Guidelines, if enacted in unchanged form, is potentially very broad.

In contrast, the scope of the substantive legal obligations is not significantly enlarged in the Draft Guidelines. To a large extent, the Draft Guidelines closely follow the rules in the AML, the Price Law and their implementing provisions. One of the few areas where the Draft Guidelines go beyond the text of the AML is, for example, where dominant companies are prohibited from requiring sub-contracting, testing and agency fees; forcing OEM manufacturing for preparations; or imposing territorial and customer sales restrictions.

Impact beyond pharmaceuticals

The Draft Guidelines also have an impact beyond the pharmaceutical sector. In particular, they may show NDRC’s latest thinking on how the various AML provisions should be interpreted.

Back in 2010, NDRC enacted the Anti-Price Monopoly Regulation, which fleshed out the AML provisions within its field of competence. Now, the Draft Guidelines contain deviations from that regulation – and many of these deviations do not seem to be sector-specific.

By way of example, the Draft Guidelines largely follow the text of the Anti-Price Monopoly Regulation to provide benchmarks for excessive pricing, namely comparison with competitors’ prices; the level of the price increase (with costs remaining stable); and a price/cost increase comparison. The NDRC decisions against the two local pharma companies released yesterday, for example, identify the excessiveness of prices by reference to the level of price increases with costs remaining stable – that is, the second above-mentioned benchmark. Now the Draft Guidelines put forward an additional, new benchmark: comparison with the price in a different region or at a different point in time. This approach is not entirely novel, as different markets were used as benchmark in past NDRC cases, but still marks a

departure from the text of the Anti-Price Monopoly Regulation.

Another example, on the upside, is that the Draft Guidelines provide for additional possibilities to justify a refusal to deal when the dominant company is not able to satisfy market demand or needs the input materials for its own production.

Since few, if any, of the deviations relate to factual aspects which are unique to the pharmaceutical sector, the real question is then why there is a need for pharmaceutical sector-specific antitrust rules in the form of the Draft Guidelines – rather than for NDRC to amend the Anti-Price Monopoly Regulation, for example.

Perhaps the answer to this question can, again, be traced back to the drug pricing reform: NDRC may have got the impression that there have been too many actual or perceived abuses of the increased pricing freedom that liberalization has brought about, and that there is a need to show tough regulatory action to tackle those abuses. The issuance of the two decisions against the local active ingredients players would seem to confirm this point.

This post originally appeared in the Kluwer Competition Law Blog.