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PRC Government Endeavors to Reduce Drug Prices

In response to increasing concern among China's population, the PRC government recently initiated a campaign to address rising drug prices. Much media attention has focused on the government's efforts in the agriculture and food sectors, but these efforts now extend to the drug industry.

The National Development and Reform Commission (NDRC), China's agency responsible for macro-economic planning including price control issues, recently issued a notice reducing the highest retail prices for more than 150 drugs. The notice took effect on December 12, 2010 and resulted in an average price drop of 19 percent.

Observers of China's pharmaceutical and health care sectors may recall that in 2009, China's Ministry of Health (MOH) developed an Essential Drug List (EDL), a list of 307 key, basic medications that all community-level hospitals in urban areas and county-level clinics in rural areas are required to have available at no additional mark-up.

The MOH's goals regarding the EDL are two-fold: one relates to cost containment and the other to quality and access. From the cost containment side, by mandating public bidding and not allowing hospital mark-ups, the EDL ensures that basic medications essential to citizens' health are widely available and at predictable prices. From a quality perspective, the inclusion of approved forms of medication on the list is aimed at ensuring that

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safely produced versions of the named drugs are available at hospitals across China. While cost containment is clearly an objective of the EDL, the government takes factors other than price into account, including whether the drugs are “basic” (such as Aspirin® and norfloxacin) and the quality and efficacy of the drugs.

By contrast, the NDRC’s recent notice is purely focused on reducing the cost of living for China’s consumers. By way of background, China’s drug pricing system is composed of three pricing mechanisms applicable to different drugs, namely government-set prices (Set Prices), prices under government guidance (Guidance Prices) and market-oriented prices (Market Prices). Both Set Prices and Guidance Prices are essentially under strict control of the government; however, Set Prices are fixed prices with no flexibility, whereas in the context of Guidance Prices, the government sets the highest retail prices. In contrast, Market Prices are set by drug manufacturers or distributors in accordance with market conditions, subject to potential intervention by the government if it determines that the prices are unreasonable.

In recognition of the quality differences among the same drug produced by different manufacturers, the government has allowed drug manufacturers to apply for independent pricing for its drugs that are subject to Set Prices or Guidance Prices, provided that such drugs can offer obviously better therapeutic results or accommodate shorter medical treatment periods and lower expense. The prices of drugs that are eligible for independent pricing are considerably higher than their counterparts in the market in most cases, and as a result, have become the target of the NDRC in its efforts to reduce drug prices. All the drugs covered by the NDRC notice had been granted the right of independent pricing, and most are produced by foreign-invested manufacturers.

Under PRC law, the prices set by the government must be in compliance with certain specified principles — e.g., the prices should cover the reasonable production cost incurred by drug manufacturers and enable manufacturers to generate reasonable profit — and should reflect the differences in terms of drug quality and therapeutic results. These principles may provide some indication to drug manufacturers as to the bases on which higher prices for their products can be justifiable. If it is clear that the production cost of a certain drug has dropped, to support a higher price, a company may need to provide further demonstration of the efficacy of the drug.

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It is also notable that the NDRC is entitled under the Price Law of the PRC to adjust the price of a drug eligible for Market Prices in the event that the price has increased or is expected to increase sharply. Technically, such adjustment may take the form of restricting the profit margin, setting the highest retail price or requiring prior application for price increase. Although no information suggests that the NDRC will exercise such right in the near future, it remains a possibility.

If you have any questions concerning the NDRC's notice or other issues related to China's life sciences industry, please contact your principal Squire Sanders lawyer or one of the lawyers listed in this Alert.

The information in this bulletin was compiled by the China offices of Squire, Sanders & Dempsey L.L.P.

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