This spring saw China making a series of legislative and policy reforms to relax the administrative controls over drug prices that have been in place for more than decade and which relate to the majority of drugs sold in China. The reforms are aimed at creating a new system whereby drug prices are mainly determined as a result of orderly market competition rather than set by the authorities.

However, the reforms do not mean that pharmaceutical companies can determine drug prices arbitrarily. In reality, they will need to give even more emphasis to assessing whether they comply with relevant laws in determining drug prices since, as a result of the reforms, the PRC antitrust authorities will establish a monitoring system and intensify investigations into any anti-competitive pricing behaviours. As part of the reform, NDRC has announced the launch of a six-month nationwide investigation into drug pricing practices.

This alert summarises the recent developments in relation to drug prices in China and sets out the implications of such developments.

**New drug pricing regime – a paradigm shift**

The main principle of new regime is its focus on market competition, which will be achieved by: (i) abolishing administratively set prices for a large number of drugs; (ii) an intensified investigation campaign in relation drug prices; and (iii) a relaxation of the rules in relation to drug price re-negotiations by hospitals.

**Abolishing administratively set prices for a large number of drugs**

The abolition of the determination of drug prices by administrative authorities has taken place at both the legislative and policy levels.

At the legislative level, the Standing Committee of the National People’s Congress released amendments to the PRC Drug Administration Law (the “Amendments”) on 24 April 2015 (available here).
In order to permit drug prices to be determined by market forces, the Amendments, which take immediate effect, remove Article 55 of the Drug Administration Law, which granted administrative authorities the power to fix prices or to set maximum retail prices for a large number of drugs. However, the way pharmaceutical companies set prices will still remain subject to the scrutiny of the PRC pricing authority under the Price Law and the Anti-Monopoly Law.

At the policy level, following public consultations, the National Development and Reform Commission (“NDRC”), together with six other authorities, formally issued an “Opinion on the Promotion of Drug Price Reform” (the “Opinion”) (available here) on 4 May 2015.

According to the Opinion, the PRC administrative bodies cease to set drug prices from 1 June 2015, save for in the following circumstances:

- for drugs which are paid for through healthcare insurance funds, the relevant medical insurance authority will, together with other authorities, propose procedures and the basis for formulating payment standards, and establish mechanisms which foster reasonable drug prices;
- for patented drugs and exclusively-produced drugs, a multilateral and transparent negotiation mechanism is to be established to determine prices;
- for (i) blood products which do not fall into the list in the healthcare insurance catalogue; (ii) immunity drugs which are centrally procured by the PRC state; and (iii) nationwide, free AIDS antiviral drugs and medical devices for family planning, prices will be determined via tendering or negotiations; and
- price caps will remain tentatively applicable to narcotic drugs and Class I psychotropic drugs.

The Opinion also calls for the regulation relating to drug prices to be strengthened, proposing the following measures:

- promulgation of specific rules by price authorities to regulate the way pharmaceutical companies set prices;
- establishing an integrated platform for multiple authorities to monitor the real transaction prices of pharmaceuticals, with a main focus on ex-factory (import) prices and actual selling/purchase prices of pharmaceuticals that do not face sufficient competition; and
- conducting research, analysis and, where necessary, special investigations into the cost-price structure of the pharmaceuticals which frequently change or widely fluctuate in price; which have significant price differences compared to international prices for the same drugs; or which have significant price differences between the same type of drugs, or between the drugs sold in different regions.

**Intensified investigation campaign on drug pricing**
The authorities’ increased focus on drug pricing is already visible due to the fact that, on the same date that the Opinion was published, the NDRC released its “Notice on Strengthening the Regulation over Pricing Behaviours on the Pharmaceutical Market” (the “Notice”) (available here), announcing the launch of a six-month nationwide investigation into drug pricing practices.

The investigation will be focused on price gouging, price collusion, abuse of a dominant market position which results in unfairly high prices, in addition to other price frauds or non-compliance with price regulations by pharmaceutical companies and hospitals, etc. The Notice requires the PRC price authorities to impose severe penalties for serious illegal pricing behaviours; to expose such illegal activities to the media; and even to prohibit the pharmaceutical companies concerned from entering into the centralised procurement market for two years.

**Relaxed rules on drug price re-negotiations by hospitals**

As part of the reforms, the General Office of the State Council issued its “Guidance Opinion on Improvement of Centralised Procurement of Drugs by Public Hospitals” (the “Guidance”) (available here) on 28 February 2015.

Whilst the Guidance does not expressly remove restrictions on price re-negotiations by public hospitals, some flexibility has been introduced in this regard. In particular, public hospitals in pilot cities are permitted to procure drugs at a price lower than the provincial bidding price. This means that public hospitals in pilot cities are not bound by provincial bidding prices, but rather can re-negotiate drug prices with pharmaceutical companies or distributors.

It remains to be seen how developments in this area will unfold, especially in terms of local practice.

**Implications for pharmaceutical companies**

The above efforts show that China is encouraging a healthcare market with increased competition, which is expected to be achieved by reducing the government’s direct control over drug prices, granting more flexibility in price-negotiations, and relaxing the rules in relation to the online sales of prescription drugs. As a result, the reforms indicate a shift in the PRC administration’s role, from controlling prices to supervising the price setting process and probing and penalising illegal pricing behaviours.

However, whilst the relaxation of administrative control over drug prices grants pharmaceutical companies more flexibility in determining prices, the companies will now face more intense scrutiny over their pricing behaviours.

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1 In May 2014, the China Food and Drug Administration issued its consultation draft on the “Administration Measures on the Supervision of the Online Operation of Food and Drugs” (the “Draft Measures”) (available here), which proposed to allow prescription drugs to be sold online, except for those specifically identified as prohibited items under a negative list. To date, the Draft Measures and the negative list have not yet been finalised or formally published.
Furthermore, some of the mechanisms imposed via the reforms may become new challenges for drug makers, especially those that are international companies. For example, under the existing drug pricing system, so-called “originators”, i.e. drugs with patents that have expired and which are mostly developed by international companies, can be priced up to 35% higher than comparable generic drugs made by domestic companies. Whilst such preferential pricing in favour of originators is provided for in the “Measures on Government Setting Drug Prices” (which have been effective since 2000 and which, although criticised by domestic pharmaceutical companies and industry associations, are still in force whilst 166 other regulations relating to the setting of drug prices have been abolished by the Opinion), the Opinion requires prices of patented drugs and exclusively-produced drugs to be determined via multilateral and transparent negotiations, involving discussions with medical institutes, insurance authorities, pharmaceutical companies, industry associations and experts. This will create challenges for manufacturers of originator drugs, who will have to negotiate with various interested parties before setting prices. In addition, the Opinion calls for investigations into the cost-price structure of drugs which are priced significantly differently compared to international prices for the same drug or where there are significant price differences between the same type of drugs. It is likely that the value of patents in determining drug prices will be scrutinised during such investigations, which may further undermine the manufacturers’ ability to charge preferential prices for originators compared to generic drugs.

In light of these changes, it is important for pharmaceutical companies to review their current pricing practices in order to ensure compliance with the relevant price and antitrust rules. For example, the relaxed rules on price re-negotiations by public hospitals may weaken any (limited) defences that were previously available to pharmaceutical companies that tried to influence distributors’ price negotiations with hospitals. Further, pharmaceutical companies with strong market power or with significant market shares in relating to certain drugs should ensure their products have a reasonable cost-price structure by properly taking into account the ex-factory (import) price, operating costs, the patent value and other cost elements, in order to avoid any potential allegations of excessive pricing. Extra cautions should also be exercised in relation to certain practices, such as bundling or applying different prices for the same drugs sold in different countries or regions since these could raise concerns under the PRC antitrust rules.