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## China Initiates National Essential Drug System

In 2009 we have witnessed substantial developments in the reform of China's health care and drug system. In April China unveiled the blueprint of the reform when the Central Committee of the Communist Party of China and the State Council jointly issued the Guidelines on Deepening the Reform of the Health Care and Drug System (Guidelines) and the State Council adopted the Key Implementation Plan for the Health Care and Drug System Reform for the Recent Period (2009-2011) (Plan). Four months later, China commenced development of the National Essential Drug (NED) system, one of the core elements of the Guidelines and the Plan, when the Opinion for Establishment of NED System (Opinion) and the Measures for Administration of NED Catalogue (Measures) were jointly issued by the Ministry of Health (MOH), the National Development and Reform Commission (NDRC), the Ministry of Industry and Information Technology, the Ministry of Supervision, the Ministry of Finance, the Ministry of Human Resource and Social Security, the Ministry of Commerce, the State Food and Drug Administration (SFDA) and the State Administration of Traditional Chinese Medicine on August 18.

As stipulated in the Opinion, the NED system requires the priority use of NEDs by hospitals at all levels, the adoption of a public bidding and collective delivery process for the procurement of NEDs by government-sponsored hospitals and the regulated pricing of NEDs, which will have significant implications for both China-based and non-China-based drug manufacturers and

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### Contacts:

[Rainer Burkardt](#)  
+86.21.6103.6360

[Nicholas Chan](#)  
+852.2103.0388

[Francis Li](#)  
+852.2103.0368

[Daniel F. Roules](#)  
+86.21.6103.6309

[Sungbo Shim](#)  
+86.10.8529.8692

[Amy L. Sommers](#)  
+86.21.6103.6308

[James S. Tsang](#)  
+852.2103.0306

[James M. Zimmerman](#)  
+86.10.8529.9735

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distributors. In 2009 each province, city and district should implement the NED system in at least 30 percent of the government-sponsored urban community hospitals and clinics as well as hospitals and clinics at the county or village level (grass-roots level hospitals) within its jurisdiction. Work on the preliminary NED system should be complete by 2011. A mature and standardized NED system should cover both urban and rural areas nationwide by 2020.

## NED Catalogue

Along with the issuance of the Opinion and the Measures, the MOH released the 2009 National Essential Drugs Catalogue for grass-roots level hospitals (Catalogue). The Catalogue lists 307 NEDs including 205 chemical drugs and biological products and 102 types of traditional Chinese medicine. It is noteworthy that the Catalogue covers only the drugs that can be used and prescribed by grass-roots level hospitals, excluding restricted drugs such as narcotics and antineoplastic drugs. According to the MOH, a special NED catalogue for such restricted drugs will be developed during the reform of government-sponsored hospitals.

In principle, the Catalogue is subject to change every three years. Any drug to be listed in the Catalogue must be a drug in the Pharmacopoeia of the People's Republic of China and subject to an existing drug standard issued by the MOH/SFDA. Therefore, it is difficult for a new drug to be included in the NED system. In addition, except for an emergency-use drug, inclusion in the NED system of any drug exclusively produced by a sole manufacturer requires a specific verification.

## Priority Use of NEDs

As a core element of the NED system, grass-roots level hospitals may not use any drugs other than NEDs. However, given the limited number of NEDs at the current stage, the system might be insufficient for the grass-roots level hospitals in certain well-developed cities such as Shanghai and Beijing. Medical experts indicated that community hospitals in Shanghai routinely use 700-800 drugs, almost twice the number of NEDs in the Catalogue. In recognition of this reality, the Opinion allows grass-roots level hospitals, during the start-up period, to use drugs on approved non-NED lists, which will be decided by provincial-level governments and registered with the Commission of National Essential Drugs, the regulatory body in charge of coordinating the establishment of the NED system and headquartered in the MOH.

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When it is necessary for grass-roots level hospitals to use additional non-NEDs, local counterparts of the MOH at the provincial level should solicit experts' opinion and select the proper drugs from the Catalogue of National Basic Medical Insurance Drugs Category A. There may be exceptions if a drug in Category B is selected to treat a special disease in a specific region. Any additional non-NED to be used by grass-roots level hospitals must be a drug that can be produced by at least two manufacturers.

As required by the Opinion, hospitals other than grass-roots level hospitals must use NEDs as a priority. Such hospitals should use NEDs at a certain percentage to be decided by the MOH and its local counterparts (Use Percentage). According to the MOH, the Use Percentage might be set as the ratio of sales revenue of NEDs against the total sales revenue of all drugs. Given that the price of NEDs will probably be lower than non-NED counterparts due to the regulated pricing, the percentage of the use of NEDs may rise.

In light of the above, manufacturers of non-NEDs, especially those relying significantly on sales through hospitals rather than retail outlets, may incur a substantial loss of market share. In contrast, NED manufacturers may have access to the booming market of grass-roots level hospitals. Under China's health care system reform, the central government will promote and support the construction of approximately 2,000 county-level hospitals within the next three years to the effect that each county has at least one hospital with standardized health care services. In addition, 29,000 new village-level clinics will be constructed and another 50,000 clinics will be rebuilt or expanded. As noted above, such hospitals and clinics may use NEDs only.

### **Public Bidding and Collective Delivery**

Pursuant to the Opinion, the procurement of NEDs by government-sponsored hospitals and clinics should be subject to an Internet-based public bidding process. In recognition of the differences among provinces, the public bidding should be organized by each province. The drug manufacturers and distributors that win the bid should deliver NEDs on a collective basis. It is noteworthy that each province may set threshold conditions in terms of, *inter alia*, drug quality or service capabilities for the candidate manufacturers and distributors participating in the public bidding.

The public bidding and collective delivery process aims to lower the price of NEDs by creating a competition mechanism and reducing redundant intermediary steps

during drug circulation, which urges NED manufacturers to provide high-quality products at a reasonable price.

In terms of the procurement of NEDs by non-government-sponsored hospitals and clinics and retail outlets, each province may develop its own rules.

### **Regulated Pricing**

As a reflection of China's determination to establish an affordable health care system, the NDRC will set guideline retail prices for NEDs. Each province needs to set, within the range of the guidelines, retail prices applicable to government-sponsored hospitals and clinics within its jurisdiction based on the public bidding results. The guideline retail prices will distinguish only different NEDs — they will not identify manufacturers. The MOH is reportedly scheduled to release the NED guideline retail prices by the end of November 2009, and industry insiders have estimated that the guideline retail prices would cause a price drop of 10 percent on average.

In addition, the Opinion requires grass-roots level hospitals to sell NEDs at the procurement price, which may lead to an additional price drop of 15 percent. It is believed that the strict restriction on the price of NEDs arises out of the principle of "exchange price for market," which means that a NED manufacturer may have access to the booming market of grass-roots level hospitals but has to make compromises in terms of pricing.

For more information on the NED system and what it means for China's health care industry, contact a member of the Squire Sanders team in any of our three China offices.

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Suite 1207, 12th Floor, Shanghai Kerry Centre, 1515 Nanjing Road West  
Shanghai 200040, People's Republic of China

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