June 26, 2017

The Honorable Li Hong
Deputy Head of Fujian Provincial Medical Reform Leading Group
Fujian Province
People's Republic of China

Dear Madame Li Hong:

Over the past four decades, the US-China Business Council (USCBC) and its 200 member companies have contributed significantly to building healthy, sustainable, and mutually-beneficial US-China commercial relations. Our members include a range of international pharmaceutical enterprises with advanced research and development capabilities, and are dedicated to the improvement of the healthcare system for Chinese citizens.

USCBC supports the goal of the Fujian Provincial Medical Insurance Management Committee Office to improve healthcare for patients as well as reduce pressures on Fujian's Basic Medical Insurance (BMI) fund. However, recent changes to Fujian's BMI pharmaceutical reimbursement settlement price[1] will undermine these goals, and decrease patient access to quality care by weakening their ability to afford the highest quality and most effective drugs available on the market. Moreover, these changes may not only adversely affect the ability of international pharmaceutical manufacturers to produce and sell high-quality drugs in China, but also the ability of domestic generic pharmaceutical manufacturers to compete on the global market.

Previous drug reimbursement rate classifications emphasized quality, efficacy, and price for BMI reimbursement. Yet, the recent changes in Fujian instead only consider price by linking the reimbursement rate for certain originator drugs to the generic's retail price, without any consideration of bioequivalence. China's State Council has requested a Generic Quality and Consistency Equivalency (GQCE) review of essential drugs by 2018 to demonstrate bioequivalence for certain domestic generic drugs; however, the linkage in Fujian occurs without any formal bioequivalence certification. It is impossible to guarantee a generic drug's clinical efficacy—or consistency with its linked originator—without first conducting a bioequivalence evaluation. This puts Fujian patients at risk of taking generic drugs that are less effective or inconsistent in their therapeutic value than the originator.

Additionally, Fujian's policies would require patients to pay the difference between an originator drug's retail price and reimbursement rate—in some cases as high as 99 percent of

[1]《关于开展以医保支付结算价为基础的药品联合限价阳光采购工作的通知》（闽医保办[2017]16 号）、《关于公布药品联合限价阳光采购医保最高销售限价和医保支付结算价有关问题的通知》（闽医保办[2017]22 号）

a drug's retail price—or to select a drug with no proven bioequivalence. When compared with the requirements before the Fujian Medical Insurance Office released Document No. 16, this increases the burden of payment on patients by 15 to 20 percent. These outcomes would ultimately decrease the efficiency of Fujian's healthcare system and put patients at risk of receiving ineffective treatment. Furthermore, selecting drugs only based on price has the potential to harm strong domestic generic manufacturers whose drugs are of a higher quality than the cheaper, yet lower-quality, drugs produced by other domestic competitors. This exclusive focus on price could decrease China's long-term competitiveness in the global pharmaceutical market.

In order to guarantee the continuity of treatment for insured patients, we recommend maintaining the 2010 Fujian Provincial Medical Insurance Supplementary Program, in order to allow current medical insurance payment standards to continue. Additionally, reforms to the healthcare system should attempt to reduce overall patient burdens, and ensure their standard of treatment is no-less than it was before reforms. These principles will contribute to the smooth implementation of healthcare reform in Fujian.

USCBC understands that the goal of Fujian's reforms is to improve the healthcare system for its citizens and to reduce pressure on the BMI fund. However, it is not necessary to de-link quality, safety, or efficacy from pharmaceutical pricing to reduce overall healthcare costs. Therefore, we respectfully recommend that Fujian suspend the implementation of the policy until the State Council GQCE review is complete. This would ensure that China's healthcare reforms properly consider drug quality, safety, and efficacy in determining reimbursement rates, and that patients have equal access to the safest and most effective drugs available.

Best regards,

Jake Parker
Vice President, China Operations
US-China Business Council