POLICIES RELEVANT TO THE PROTECTION OF THE RIGHTS AND INTERESTS OF INNOVATORS FOR THE ENCOURAGEMENT OF INNOVATION IN DRUGS AND MEDICAL DEVICES (DRAFT FOR COMMENT)[1]

1. **A drug-patent linkage system will be established.** Upon filing the registration application, the applicant for drug registration should submit a declaration on the relevant rights involved that it knows or should know. Where the applicant seeks to challenge the relevant drug patent, the applicant must declare non-infringement of the relevant drug patent and give notice to the patentee of the relevant drug patent within 20 days after filing the registration application. If the patentee of the relevant drug patent finds infringement of its patent, the patentee should file a patent infringement suit with the judiciary within 20 days after receiving notice from the applicant and should give notice to the drug review institution. After receiving the relevant documents certifying the filing of the patent infringement lawsuit with the judiciary, the drug review institution may set an approval-standstill period no longer than 24 months, during which period, the technical review of any drug already under review will not stop. During the approval-standstill period, if the litigants settle the dispute or if the judiciary renders an effective judgment finding infringement or non-infringement, the drug review institution should grant or deny drug marketing approval based on the settlement between the litigants or the relevant effective judgment by the judiciary. At the end of the approval-standstill period, if the judiciary has not rendered a judgment finding infringement, the drug review institution may approve drug marketing. If in its filed drug application the applicant does not declare any relevant patent involved, and if the patentee files suit for infringement, the drug review institution will institute an approval-standstill period in accordance with the judiciary's docketing procedure. Any intellectual property litigation arising out of the marketing and sales of drugs will be adjudicated by the judiciary.

2. **The drug trial data protection system will be perfected.** Upon the filing of a drug marketing application, the applicant may also file for trial data protection. A 6-year data protection period will be set for innovative drugs approved for marketing. A 10-year data protection period will be set for innovative drugs that are also orphan drugs or drugs for children; A 10-year data protection period will be set for orphan drugs or drugs for children with improvement over available drugs. A 1.5-year data protection period will be set for generic drugs that successfully invalidate patents and for the first domestic generic drug based on an originator that has been marketed abroad. A data protection period commensurate with its classification will be set for new drugs for which marketing approval and data protection in China are sought within one year after receiving marketing approval from the European Medicines Agency, or in the U.S. or in Japan. For [new drugs for which] marketing approval in China is sought more than 1 year after [receiving marketing approval from the European Medicines Agency, or in the U.S. or in Japan], the amount of time in excess will be deducted from the data protection period. If the balance is less than 1.5 years after such deduction, a data protection period of 1.5 years will be granted. The data protection period starts from the date of drug marketing approval. During the data protection period, the review institution will not approve any marketing application of the same type by other applicants, except for data obtained by the same applicant.

3. **The civil servants' confidentiality obligations will be enforced.** All staff participating in the review and approval process for drug and medical device registration and staff participating in verifications, inspections, and supervisions will have confidentiality obligations with respect to the technical secrets and trial data submitted by the applicant. Anyone in violation of his confidentiality obligations will be disciplined and publicized by the authorities in charge of drugs and medical devices in accordance with relevant laws and regulations.

[1] *See* http://www.sfda.gov.cn/WS01/CL0087/172606.html?from=timeline&isappinstalled=0 (published on May 12, 2017).

4. **A catalogue of marketed drugs will be compiled.** All drugs approved for marketing in China will be included in the Catalogue of Marketed Drugs in China, which will specify the properties of innovative drugs, new drugs with substantial improvement over available therapy, and generic drugs that have passed the quality and bioequivalence evaluations, and which will specify, for all drugs listed, the active pharmaceutical ingredients, the dosage forms, the specifications, and the holder of the marketing licenses, as well as information on exclusive rights such as patent coverage, monitoring period, and data protection measures.