COMMENTS FROM THE EUROPEAN UNION CONCERNING NOTIFICATION

G/TBT/N/CHN/1169

WORK PROGRAM FOR THE REFORM OF CHEMICAL DRUGS REGISTRATION CATEGORY

The European Union (EU) would like to thank the Chinese authorities for providing the opportunity to comment on the proposed *"Work programme for the Reform of Chemical Drug Registration Category*" which was notified on 26 February 2016.

The EU takes note of the efforts and intention of the Chinese authorities to improve and modernise the regulatory system in China. The ongoing efforts to reform the Chemical Drug Registration provide further opportunities to develop a robust regulatory framework that is increasingly aligned with international standards.

The EU welcomes the broad objectives of the "*Reform of Chemical Drug Registration*", in particular, the goals of encouraging innovation and raising the quality, safety and effectiveness of drugs marketed in China. Appropriate implementation of these goals could have tangible benefits for Chinese patients, including faster access to new and innovative therapies. However, the EU would like to raise its concerns in relation to the registration categories of chemical drugs introduced by the Reform:

The draft new registration categories of chemical drugs introduced by the "*Chemical Drug Registration*" classification include the following:

- Category 1: Innovative drugs not marketed in China and abroad;
- Category 2: New improved drugs that are not marketed in China and abroad;
- Category 3: Imitation of drugs that are marketed overseas but unavailable domestically;
- Category 4: Imitation of drugs that are marketed domestically,
- Category 5: Application for the domestic marketing authorisation of drugs marketed overseas.

In addition, the reform work programme defines the registration procedure based on the above classification as follows: "*The new registrations of Categories 1 & 2 shall follow the registration procedures for **new drugs** stipulated in the Measures for the Administration of Drug Registrations. The new registrations of Categories 3 & 4 shall follow the registration procedures for imitation drugs stipulated in the Measures for the Administration of Drug Registrations. The new registrations of Category 5 shall follow the registration procedures for imported drugs stipulated in the Measures for the Administration of Drug Registrations. The reform work programme also sets different monitoring periods for different sub-categories of **new drugs**, varying from 3 to 5 years*."

The Reform introduces a new definition of a "*new drug*" - defining it as "*one that has never been marketed in any country*". According to the EU, this definition is not clear and open to interpretation. The EU would appreciate further clarification from the Chinese authorities on what is meant by 'drugs not marketed in China and abroad'. In particular, the EU would like to know whether a *'new drug*' would need to be

authorised in China before it is authorised elsewhere in the world to be included in in categories 1 & 2? The EU is concerned that drugs approved or marketed first outside of China may receive slower regulatory consideration, and not benefit from the exclusivity granted to drugs marketed first in China.

For these same reasons the EU also believes that the notified draft may create disincentives to bring innovative drugs to China and undermine the very important progress that China has made to integrate into the global drug development system.

The EU kindly invites China to clarify the draft categories of "*new drugs*" and to provide reassurances regarding the above concerns.

The EU would be grateful if the above-mentioned comments would be taken into account and replied to before adoption of the notified text.

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