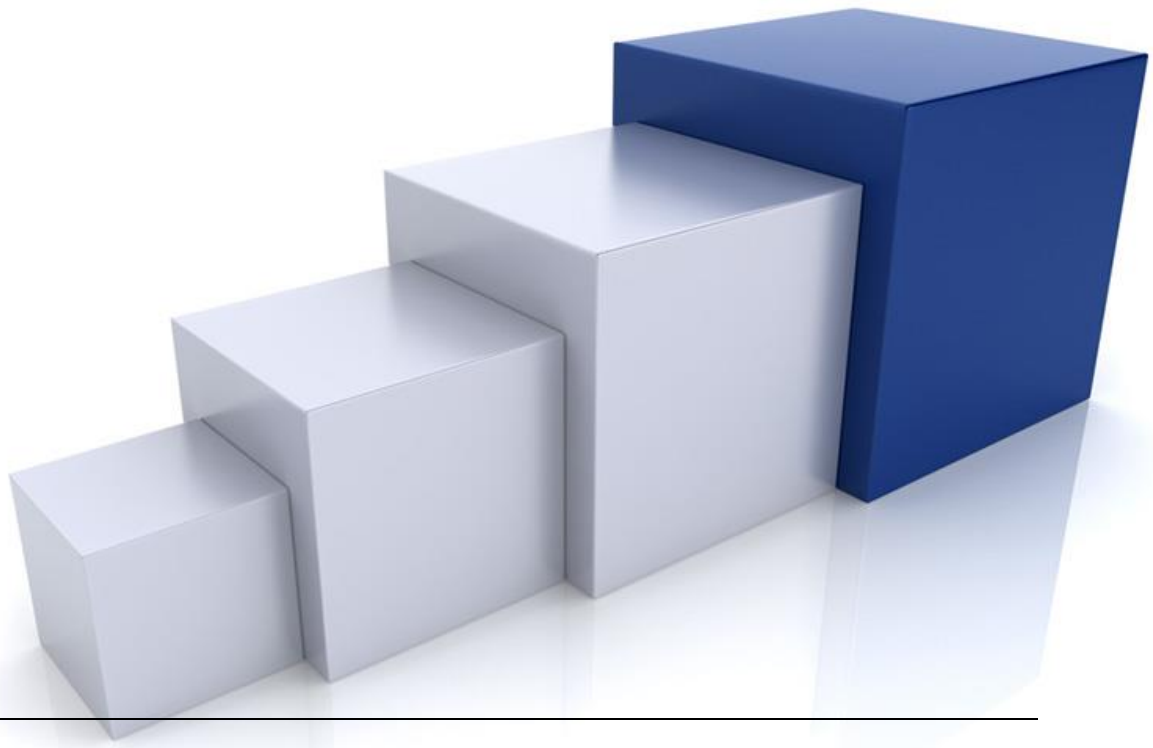
ALLEN & OVERY

# NMPA Seeks Comment on Draft Regulations of Drug Registration, Manufacturing and Distribution

October 2019

# Contents





*On 30 September 2019, the National Medical Products Administration (the **NMPA**) published three sets of draft regulations seeking public comment. They are the Draft Drug Registration Regulations, the Draft Manufacturing Regulations and the Draft Drug Distribution Regulations. The Ministry of Justice further updated these Draft Regulations on 15 October 2019 and is seeking public comments on these further amended Draft Regulations. The new commenting deadline on these further amended Draft Regulations is now 14 November 2019.*

Theses draft regulations reflect most of the changes to the amended Drug Administration Law, which will take effect on 1 December 2019, including the marketing authorization holder system, automatic approval for clinical trials, compassionate use of drugs, conditional marketing approval and the abolition of GMP and GSP certificates.

In addition, the draft regulations also bring in some new changes that may be relevant to IP, which are summarized below.

## 1. New classification of drugs

Drugs in China are separated into three large categories: chemical drugs, biologics and traditional Chinese medicine for registration purposes. The current classification is set forth under the Drug Registration Regulations of 2007 (the **2007 Registration Regulations**). The Work Plan on the Reform of Chemical Drug Registration Classification (released on 4 March 2016 by the NMPA) modified the classification of chemical drugs. Article 5 of the Draft Drug Registration Regulations proposes a revised classification system. A comparison is as follows.

| | Current Classification | Proposed Classification |
|---|---|---|
| Chemical drugs | 1. Innovative drug not marketed either in China or overseas<br>2. Modified new drug not marketed either in China or overseas<br>3. Generic drug of an originator's drug which has been marketed overseas but not in China<br>4. Generic drug of an originator's drug which has been marketed in China<br>5. Imported drug that has been marketed overseas | ▪ Innovative drug;<br>▪ Modified new drug;<br>▪ Generic drug; and<br>▪ Chemical drug that is marketed overseas but not in China. |
| Biologics | ▪ Biologics are classified into two groups: therapeutic biologics and preventive biologics.<br>▪ Each group is further classified into 15 categories in Annex 3 of the 2007 Registration Regulations. | ▪ Innovative biologics;<br>▪ Modified new biologics;<br>▪ Biologics already marketed in China (including biosimilar and other biologic not regulated as biosimilar); and<br>▪ Biologics marketed overseas but not in China. |

## 2. New application pathways

The 2007 Registration Regulations provide pathways for new drug applications, generic drug applications and imported drug applications (see article 12 of the 2007 Registration Regulations). The Draft Drug Registration Regulations adopt a new drug approval framework which include new drug applications (NDA), abbreviated new drug applications (ANDA), applications for over-the-counter drugs (OTC) (see articles 35, 36 and 37 of the Draft Drug Registration Regulations). The proposed application pathways correspond to the proposed classes of drugs.

## 3. Fast-track marketing approval

Chapter 4 of the Draft Drug Registration Regulations covers the rules on fast-track approval for drugs. It sets out four types of fast-track approval pathways: breakthrough therapy, conditional approval, priority review and special review.

An innovative drug applicant may proceed on the breakthrough therapy track during clinical trial, if the innovative drug is useful for treating serious life-threatening diseases or where diseases seriously affect the quality of life, and if there is no effective therapy for such diseases or the innovative drug is sufficiently proven to be significantly more advantageous than the existing therapy. See article 66 of the Draft Drug Registration Regulations.

Conditional approval or accelerated approval tracks are intended for the following drugs under clinical trials: (i) drugs for treating serious life-threatening diseases with no effective therapy where the efficacy and clinical value of the drugs are demonstrated by clinical trial data; (ii) drugs urgently needed for public health emergencies where the efficacy and clinical value of the drugs are demonstrated by clinical trial data; or (iii) vaccines urgently needed, either for major public health emergencies or as determined by the National Health Committee, for which the benefit of a conditional approval outweighs their risk. See article 67 of the Draft Drug Registration Regulations.

An applicant may apply for a priority review of drugs including: (i) drugs on the breakthrough therapy track; (ii) drugs on the conditional approval track; (iii) new drugs with limited supply and urgent clinical needs, new drugs for the prevention and treatment for major contagious diseases and orphan drugs; (iv) new types, formulations and dosage forms of pediatric drugs; and (v) vaccines urgently needed for preventing diseases and innovative vaccines. See article 72 of the Draft Drug Registration Regulations.

The NMPA may initiate special review proceedings during major public emergencies. See article 75 of the Draft Drug Registration Regulations.

## 4. No market exclusivity legislation

Several provisions of the 2007 Registration Regulations are omitted in the Draft Drug Registration Regulations, including provisions on new drug monitoring periods (article 66 of the 2007 Registration Regulations), patent-related rules (articles 18 and 19 of the 2007 Registration Regulations), and the currently unenforced data protection (article 20 of the 2007 Registration Regulations). Although the rules on new drug monitoring periods and data protection are still technically available via the Implementing Regulations of the Drug Administration Law (see articles 33 and 34), we expect these provisions to be further amended or revised due to the new amendment to the Drug Administration Law.

## 5. Abolition of GMP and GSP certificates

The abolition of GMP and GSP certificates first appeared in the amended Drug Administration Law and is now incorporated into these draft regulations. Although drug manufacturers and distributors are no longer required to obtain separate GMP and GSP certificates, they still need to meet the GMP and GSP standards in order to obtain a Drug Manufacturing Certificate and a Drug Distribution Certificate, respectively (see articles 6 and 7 of the Draft Manufacturing Regulations, and article 8 of the Draft Drug Distribution Regulations).

http://www.nmpa.gov.cn/WS04/CL2104/359096.html
(NMPA publication of the Draft Regulations)

http://zqyj.chinalaw.gov.cn/index
(Ministry of Justice publication of the Draft Regulations)

# FOR MORE INFORMATION PLEASE CONTACT

## *China*

David Shen
Partner, Shanghai
Tel +86 21 2036 7138
david.shen@allenovery.com

Allen & Overy LLP
Shanghai office
15F, Phase II, Shanghai IFC
8 Century Avenue
Pudong, Shanghai 200120
China

GLOBAL PRESENCE

Allen & Overy is an international legal practice with approximately 5,500 people, including some 550 partners, working in more than 40 offices worldwide. Allen & Overy LLP or an affiliated undertaking has an office in each of:

| | | | | |
|---|---|---|---|---|
| Abu Dhabi | Bucharest (associated office) | Hong Kong | Munich | Singapore |
| Amsterdam | Budapest | Istanbul | New York | Sydney |
| Antwerp | Casablanca | Jakarta (associated office) | Paris | Tokyo |
| Bangkok | Dubai | Johannesburg | Perth | Warsaw |
| Barcelona | Düsseldorf | London | Prague | Washington, D.C. |
| Beijing | Frankfurt | Luxembourg | Rome | Yangon |
| Belfast | Hamburg | Madrid | São Paulo | |
| Bratislava | Hanoi | Milan | Seoul | |
| Brussels | Ho Chi Minh City | Moscow | Shanghai | |