

**China Insight**

# Outlook on the New Standards of Good Manufacturing Practice for Veterinary Drugs

Dear Sir or Madam,

Please find below an outlook on the new standards of good manufacturing practice for veterinary drugs.

Kind regards,  
**CMS, China**

On 21 April 2020, the Ministry of Agriculture and Rural Affairs of the People's Republic of China ("**MOA**") issued the *Standard of Quality Management in the Production of Veterinary Drugs (2020 Revisions)* (the "**New GMP**"), which took effect on 1 June 2020. The veterinary drug good manufacturing practice is the basic requirements and guidelines for veterinary drug production management and quality control in the People's Republic of China (the "**PRC**"). It is the legal technical standards commonly used by countries around the world to monitor and manage the entire process of veterinary drug production.

## 1. Historical Changes and Purposes of the New GMP

The original veterinary drug good manufacturing practice (the "**Original GMP**") was promulgated in 2002. Since its implementation (i.e. 19 June 2002), it has played an important role in regulating the behaviour of veterinary drug manufacturing enterprises and promoting the healthy development of the veterinary drug industry. However, with the economic, social and technology development, the Original GMP has become increasingly unsuitable for the actual needs of veterinary drug industry development and management. At present, low-level repetitive small-scale and low-efficiency production enterprises result in a waste of resources, overcapacity, and low industrial concentration, which lead to product homogeneity and vicious competition. The quality of some veterinary drugs is uneven, posing hidden risks to animal product quality and safety. In addition, a veterinary drug quality management system is a common practice and effective means in the PRC and EU whilst the Original GMP lacks relevant requirements. Thus, many enterprises in practice have to rely on their experiences to manage, which is not conducive to the control of quality risks.

Considering the situations mentioned above, the New GMP optimizes the structure, refines the content, and improves the guidance and operability comparing to the Original GMP. It has 13 chapters and 287 articles, and it is aimed at supervising the production of veterinary drugs from the whole process of personnel, plant, equipment, materials, documents, production process, sales, self-inspection, etc., and ensures the quality and safety of veterinary drugs.

## 2. Improvements and Enhancements of the New GMP

a) Major changes to the overall structure

The New GMP is promulgated based on the Original GMP and also refers to the *Pharmaceutical Good*

*Manufacturing Practice of the PRC (2010 Revisions)*, effective on 1 March 2011, and relevant regulations on veterinary drugs of the Pharmaceutical Good Manufacturing Practices implement in European Union ("EU"). Subject to the production process and characteristics of different types of veterinary drugs, and according to an Announcement (No. 292) of MOA released on 13 May 2020, there are special requirements for the production quality management of five (5) types of veterinary drugs including sterile veterinary drugs, non-sterile veterinary drugs, veterinary biological products, raw materials, and traditional Chinese medicine preparations have been formulated and will come into effect on the same day as the New GMP as supporting documents of the New GMP.

b) Increasing production standards for sterile veterinary drugs and veterinary biological products

According to the risk of exposure during production, the New GMP sets four(4) levels of cleaning zone as in A, B, C and D of sterile veterinary drugs and veterinary biological products, adds the requirements for online monitoring of the production environment, focus on the combination of dynamic and static control, which the Original GMP only has the standards for static testing of air cleanliness during the production process of veterinary drugs, and enhances product quality assurance level.

c) Increasing requirements of the production facilities for special veterinary drugs

The New GMP provides different requirements for the production of different types of veterinary drugs:

- (1) the production of hormonal veterinary drugs shall use independent production sites, production facilities, air purification systems, and shall be strictly separated from other veterinary drug production areas;
- (2) the production of topical pesticides for external use and environmental disinfectants shall use an independent building, production facilities, and equipment, and shall be strictly separated from the production of other types of veterinary drugs;
- (3) the powder and premix can share the same production line whilst they shall be separated from the bulk packaging production line;
- (4) veterinary biological products shall be produced separately according to the types and nature of microorganisms;
- (5) animal rooms for inspection and the production sites shall be set up separately and each shall be in a separate building;
- (6) veterinary drug production sites shall not be used to produce non-veterinary drugs.

d) Enhancing and refining software management

The New GMP strengthened for requirements for enterprise quality management by involving the control of changes, deviation handling, corrective and preventive measures, product quality review analysis, continuous stability inspection plan, design confirmation, and other systems to ensure the maximum quality management of veterinary drug products.

e) Improving the requirements for qualification and technical skills of professionals

The New GMP provides criteria and requirements of quality management personnel engaged in veterinary drug production. In order to provide a basis for tracing or pursuing a quality defect of veterinary drugs, it further clarifies certain personnel's roles and responsibilities by specifying that the primary responsible person for the production management of a manufacturing enterprise shall be the person-in-charge of that enterprise. In addition, the New GMP details and requires a manufacturing enterprise to appoint respectively the person-in-charge of its production management and the person-in-charge of its quality management, whilst the Original GMP only generally required a manufacturing enterprise to establish a quality management department and a production management department.

f) Improving the requirements of biosecurity control by production enterprises

To ensure biosecurity, strict requirements (including plant, facility, equipment safety, discharge of waste, live toxic wastewater and discharged air) are further stipulated for the production and inspection of veterinary biological products under the New GMP.

g) Improving the documentation management requirements

The New GMP refines the management process and content of main documents relating to quality standards, technological procedures, batch production records, etc. which enhances the guidance and operability for veterinary drug production enterprises.

### 3. Implementation of the New GMP and Transitional Period

The New GMP has been implemented since 1 June 2020. According to an Announcement (No. 293, the “**Announcement**”) published by the MOA on 6 May 2020, the requirements and specific arrangements for the transition period are described as follows:

- a) According to the Announcement, all veterinary drug manufacturing enterprises shall meet the requirements and criteria under the New GMP prior to or by 1<sup>st</sup> June 2022.
- b) For those veterinary drug manufacturing enterprises (production sites) that cannot meet such requirements, their current veterinary drug production licenses and veterinary drug GMP certificates are still valid till no later than 31<sup>st</sup> May 2022.
- c) Since 1<sup>st</sup> June 2020, any newly established veterinary drug manufacturing enterprises and veterinary drug manufacturing enterprises that intend to rebuild, expand, or relocate their production sites shall be in line with the requirements of the New GMP.
- d) Since 1<sup>st</sup> June 2020, the provincial animal husbandry and veterinary authorities will accept applications from a veterinary drug manufacturing enterprise, inspect and examine veterinary drug manufacturers in accordance with the New GMP.
- e) The veterinary drug production license and veterinary drug GMP certificate will be valid for a period of five (5) years.
- f) If a veterinary manufacturing enterprise which currently holds the veterinary drug production license and veterinary drug GMP certificate in accordance with the Original GMP applies for renewal, upon the inspection and approval of the competent animal husbandry and veterinary authority, such license and certificate should be valid until 31<sup>st</sup> May 2022.
- g) For applications that have been accepted before 1st June 2020 and for which veterinary drug production licenses and veterinary drug GMP certificates are obtained in accordance with the Original GMP, such license and certificate should be valid until 31<sup>st</sup> May 2022.

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In case you have questions or for further information, please contact the authors of this newsletter:



**Nicolas Zhu**  
Partner  
Head of Lifesciences Sector Group  
CMS, China  
T + 86 21 6289 6363  
E [nicolas.zhu@cmslegal.cn](mailto:nicolas.zhu@cmslegal.cn)



**Jennifer Zhang**  
Associate  
  
CMS, China  
T +86 21 6289 6363  
E [jennifer.zhang@cmslegal.cn](mailto:jennifer.zhang@cmslegal.cn)

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 3108 Plaza 66, Tower 2, 1266 Nanjing Road West, Shanghai 200040 P.R.China  
上海市南京西路 1266 号恒隆广场 2 期 3108 室

 Phone/ 电话: + 86 21 6289 6363

Fax/ 传真: + 86 21 6289 0731

 Web/ 网址: <https://cms.law/en/chn/>

 Email/ 电邮: [info@cmslegal.cn](mailto:info@cmslegal.cn)



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