Statement

We, Taizhou Mabtech Pharmaceuticals Co., Ltd, hereby state that GMP certificate is not applicable any more in China as per Chinese authority requirement. The supporting reasons are described as following:

1.To support the Chinese drug administration law, Chinese authority released an announcement in 2019 to explain some events including that GMP certificate is not applicable in the future.

The announcement is published in the Chinese authority website. Kindly check the screenshot of the website as Annex 1.

2.Currently the actual authority GMP inspection format is similar to Europe and FDA. The provincial authority is mainly responsible for GMP inspection. After inspection is completed, drug authority will release an announcement in its website to inform public the results of all inspections conducted during a period. Kindly check the GMP compliance inspection resluts published in the local drug authority website for the manufacturer in Annex 2. It is the screenshot of website with English translation.

Digitally signed by Guțan Ghenadie
Date: 2023.08.15 09:43:50 EEST
Reason: MoldSign Signature
Location: Moldova

NMPA Issued the Announcement on Issues Pertaining to the Implementation of the Drug Administration Law of the People's Republic of China

Updated: 2019-11-29

On November 29, 2019, NMPA issued the Announcement on Issues Pertaining to the Implementation of the *Drug Administration Law of the People's Republic of China* (2019 No. 103), which reads as follows:

Revised and adopted by the Twelfth Session of the Standing Committee of the 13th National People's Congress on August 26, 2019, the revised Drug Administration Law of the People's Republic of China (hereinafter referred to as DAL) shall be implemented as from December 1, 2019. NMPA is stepping up work on the development, formulation and revision of supporting regulations, normative documents and technical guidelines, which will be released in accordance with procedures. We hereby announce the issues pertaining to the implementation of the newly revised DAL as follows:

I. The Drug Marketing Authorization Holder System

The newly revised DAL takes the drug marketing authorization holder (MAH) system into full swing. Starting from December 1, 2019, all undertakings or drug R&D institutions holding drug registration certificates (drug approval numbers, import drug registration certificates, or medical product registration certificates) shall be taken as drug MAHs, who should strictly perform their corresponding obligations, and take responsibility for drug safety, effectiveness and quality controllability in the whole process of drug R&D, production, distribution and use.

II. Record-filing management of clinical trial institutions

As from December 1, 2019, drug clinical trial institutions (DCTIs) shall be, invariably, subject to record filing management. DCTI-qualification applications accepted before December 1, 2019, with pending examination & approval results, shall be subject to record filing per the current regulations.

III. Requirements for drug GMP and GSP administration

As from December 1, 2019, drug GMP and GSP certifications shall be cancelled, and the corresponding applications / certificates shall be no longer accepted / issued. Certification applications accepted before December 1, 2019 shall be processed in accordance with the relevant provisions of the original drug GMP and GSP certification. To applications with on-site inspection completed and conformance to requirements before December 1, 2019, drug GMP and GSP certificates can be issued. On-site inspection shall be carried out even after December 1, 2019, where the current regulations require it, and the corresponding results shall be notified to the enterprise; non-compliance found in the inspections shall be dealt with in accordance with regulations pursuant to the Law.

IV. Associated review & approval for chemical APIs

tarting from December 1, 2019, no drug registration certificate will be issued for chemical APIs, whose manufacturers shall register on the AEP (APIs, pharmaceutical excipients, packaging materials and containers in direct contact with pharmaceuticals) registration platform for associated review & approval.

V. Investigation and prosecution of drugrelated illegal activities

For illegal activities occurred before December 1, 2019 in drug R&D, production, distribution, and use, the former DAL (unrevised) shall apply, barring those deemed by the newly revised DAL as overestimated or underestimated activities, for which the newly revised DAL shall prevail. For illegal activities occurred after December 1, the newly revised DAL shall apply.

Drug regulatory authorities at all levels must resolutely implement the Four Strictest (*Strictest Standards, Regulation, Punishment, and Accountabilty*) Requirements for drug safety, strengthen the publicity and implementation of the newly revised DAL, further strengthen supervision and inspection, urge enterprises to continue to comply with production & distribution protocols, and strictly investigate and punish all kinds of illegal acts, to effectively safeguard medication safety for the general public.

江苏省药品监督管理局药品GMP符合性检查结果公告（2021年第58号）

发布时间：2021-08-03

根据《药品管理法》、《药品生产监督管理办法》有关规定，经现场检查并综合评定，现将泰州迈博太科药业有限公司《药品生产质量管理规范》符合性检查结果公告。

序号	企业名称	生产地址	检查范围	检查时间	检查结论
1	泰州迈博太科药业有限公司	泰州市中国医药城口泰路西侧，陆家路东侧G79幢	治疗用生物制品（注射用英夫利西单抗，冻干粉针剂）	2021.03.09-2021.03.14	符合

江苏省药品监督管理局

2021年8月3日

English translation

Announcement on GMP Compliance Inspection Result of Jingsu Medical Products Administration(No.58 of 2021)

According to Chinese Drug Administration Law and Measures for the Supervision and Administration of Drug Production, hereby announce the GMP compliance result of Taizhou Mabtech Pharmaceuticals Co., Ltd after site inspection and comprehensive evaluation.

No.	Manufacturer	Production address	Inspection range	Inspection date	Conclusion
1	Taizhou Mabtech Pharmaceuticals Co.,Ltd.	G79 Building, East of Lujia Road and West of Koutai Road, Chinese Medicine Center, Taizhou, Jiangsu, China	Biological product for treatment (infliximab for injection, lyophilized powder)	Mar, 9, 2021 - Mar, 14, 2021	Compliance

Jingsu Medical Products Administration

August 3,2021