Medical writing in China: Trends and opportunities

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Abstract
The Chinese pharmaceutical regulatory landscape and medical publication policies have gone through drastic changes in recent years, and they continue to evolve. These changes provide great opportunities and many challenges to medical writers in China, and they affect the global medical communications strategy of multinational pharmaceutical companies and global medical communications agencies. Seasoned medical writers who are fluent in both English and Chinese are becoming essential to multinational pharmaceutical companies interested in the Chinese market as well as to Chinese companies striving to enter the global market. Meanwhile, the demand for ethical medical writing and editorial services remains high. In this article, I share my observations on the current trends, opportunities, and challenges facing medical communications professionals in China.

Background
The Chinese pharmaceutical industry has experienced tremendous growth in the past decade, and China has become the second largest pharmaceutical market in the world. According to a report published by the US Department of Commerce, the Chinese pharmaceutical market is projected to grow from $108 billion in 2015 to $167 billion by 2020.[1] Meanwhile, China's total healthcare expenditures have increased rapidly and are projected to almost double by 2020 (Figure 1).

Behind the rapid growth of the Chinese pharmaceutical industry are two forces. One is that multinational pharmaceutical companies continue to increase their investment in China and the second is that a growing number of Chinese biopharmaceutical companies strive to improve their reach both at home and globally.

In the past, global and local pharmaceutical companies have faced many challenges in China. One of the main challenges has been the uncertainty of Chinese drug regulation. The Chinese government's unique regulatory requirements, the lack of clear guidance, and the ever-changing rules often cause headaches for both foreign and domestic companies.

However, things began to change in June 2017. During the International Council on Harmonisation meeting in Montreal between May 31 and June 1, the China Food and Drug Administration (CFDA), which is the Chinese pharmaceutical regulatory authority, was approved as a regulatory member.[2] This marks a significant milestone in China's pursuit of regulatory modernisation. It also provides many opportunities and challenges for all pharmaceutical companies operating in China.

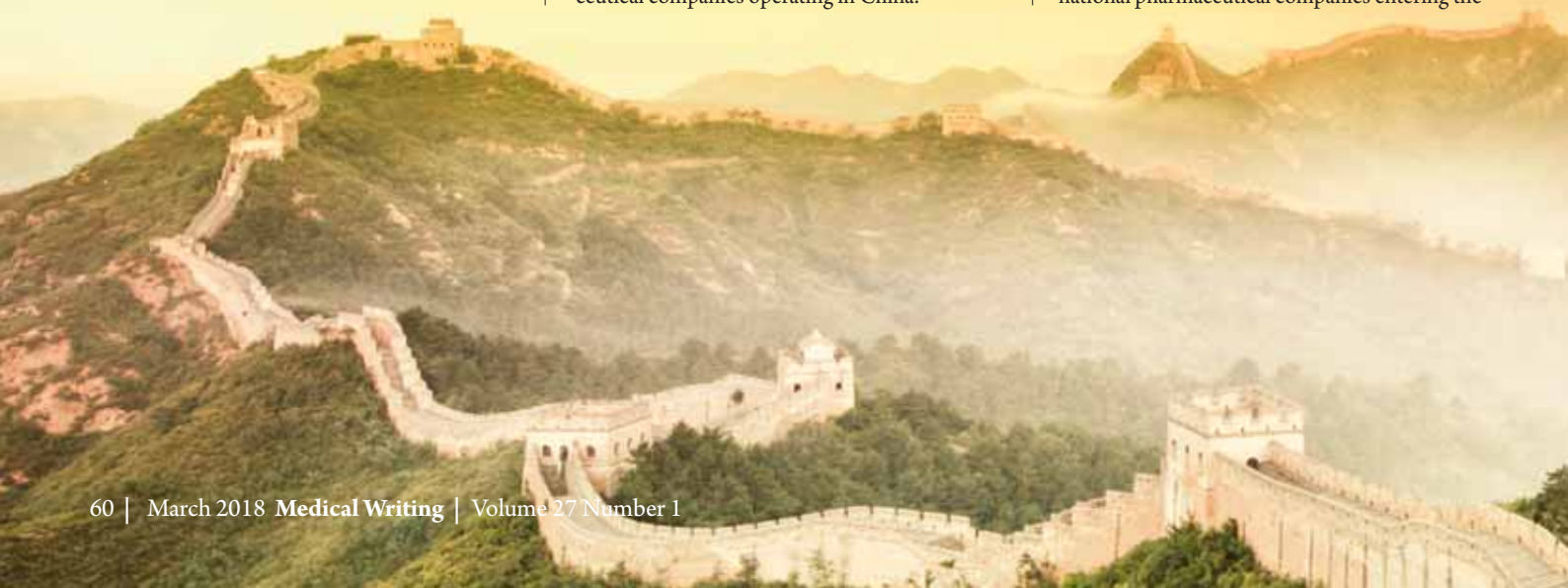
Meanwhile, the Chinese Center for Drug Evaluation, a division of the CFDA, is leading an effort to translate many of the US FDA guidelines into Chinese. This will serve two purposes. First, this will help the staff at CFDA and the Chinese Center for Drug Evaluation learn the lessons and gain from the experience of the US FDA. After all, the regulatory bodies face many similar challenges. Second, the translated documents will greatly help Chinese pharmaceutical companies planning to bring their products to global markets.

The recent changes in the Chinese regulatory landscape will inevitably affect many functional areas of the Chinese pharmaceutical industry. Along with manufacturing and clinical trial management, medical writing – especially regulatory medical writing – will face drastic changes.

The rise of the Chinese regulatory medical writing profession

The past
Regulatory medical writing is a new profession in China. This is not because the need for regulatory medical writing did not exist in China a decade ago. Rather, regulatory medical writing was only recently recognised as a profession.[3] In the past, most Chinese pharmaceutical companies did not have dedicated medical writing employees. Regulation-related medical writing was often managed by larger departments, such as medical affairs or clinical development.

Employing professional regulatory medical writers to prepare regulatory documents is believed to have been introduced by multinational pharmaceutical companies entering the



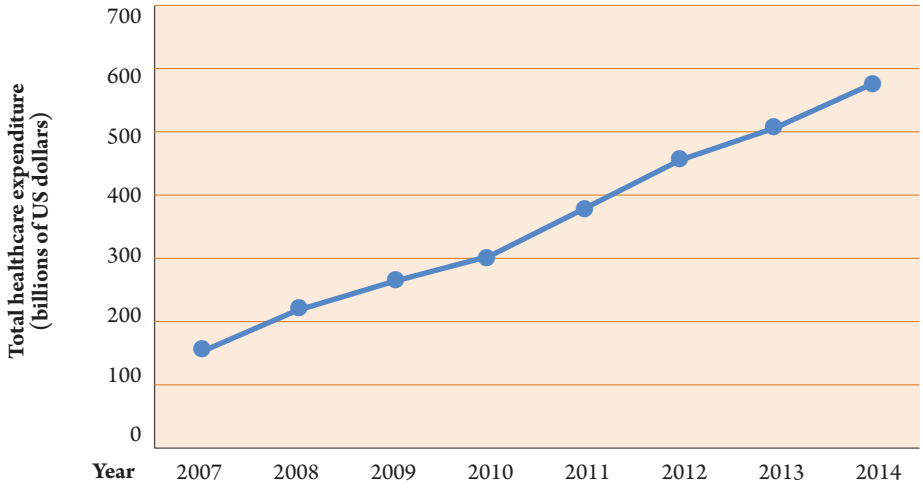


Figure 1. China's total healthcare expenditure from 2007 to 2014 in current US dollars
Data are from the WHO[15]

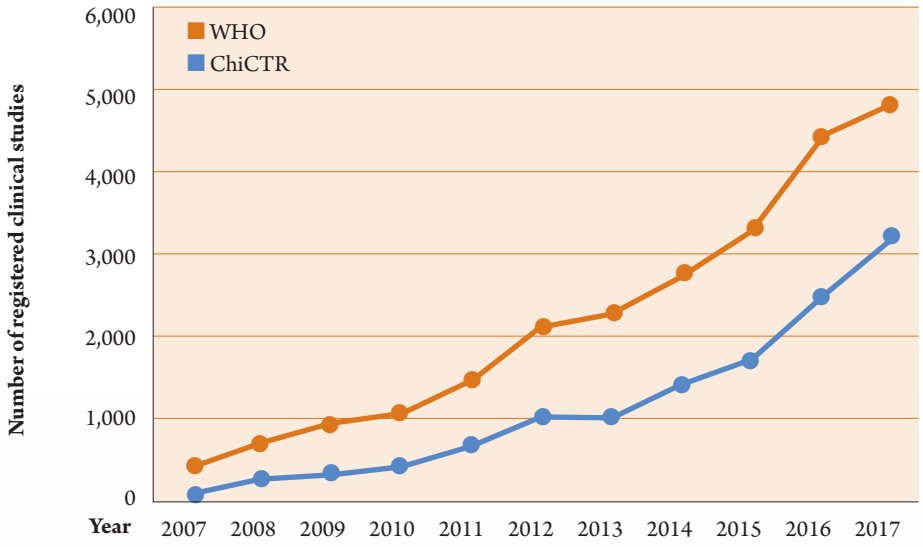


Figure 2. Number of clinical studies recruiting Chinese subjects
Data are from the WHO[16] and the Chinese clinical trial registry (ChiCRT).[17]
Data for 2017 are up to December 12.

Chinese market. Even though the companies had medical writers based in the headquarters developing documents for global submissions, they still needed a bilingual local work force to work with internal colleagues and the CFDA. Regulatory medical writers who can speak and write well in both English and Chinese are in great demand.

At first, global pharmaceutical companies turned to China-based contract research organisations (CROs) to help with medical writing-related projects. The quality of the deliverables from these CROs, however, was inconsistent when medical writing was not one of their core competencies. Gradually, multinational pharmaceutical companies, especially those that had set up research and development centres in China, started to build their own local medical writing teams. As they began to hire and train Chinese medical writers, the concept of professional medical writing became better known to the Chinese pharmaceutical industry.

The present

Although accurate data are lacking, the number of professional regulatory medical writers in China is generally believed to have been fewer than a few dozen a few years ago, most of whom worked for multinational pharmaceutical companies and global CROs.[4] Current estimates suggest at least a few hundred Chinese regulatory medical writers work for foreign companies and local companies alike, and the number is expected to grow rapidly in the next few years.

To support the growing number of local medical writers, in 2013 a group of medical writers based in China proposed and subsequently established the China Medical Writers Community (CMWC).[5] The formation of CMWC marks the birth of regulatory medical writing as a profession in China. Membership in the CMWC has grown steadily. In addition to biannual educational events, CMWC members actively share knowledge and expertise online through a social media group.

In addition to multinational pharmaceutical companies and global CROs, Chinese biopharmaceutical companies and local CROs are

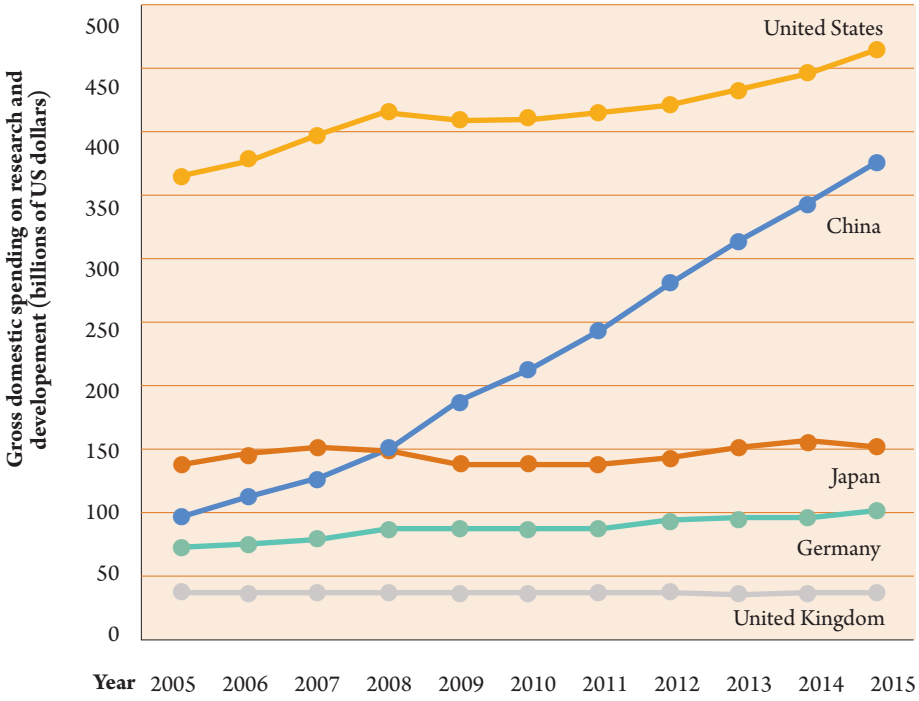


Figure 3. China's gross domestic spending on research and development
Data are from the Organisation for Economic Co-operation and Development.[18]

also contributing to the growth of the regulatory medical writing profession in China. Many of these Chinese biopharmaceutical companies and CROs are startups founded and managed by Chinese overseas returnees. Before returning to China, the owners and the management teams of these companies often had worked at global pharmaceutical giants for many years. Many of them have decades of research as well as management experience, and they understand the importance of high-quality clinical and regulatory documents in drug development and marketing submissions. When they need clinical trial protocols, clinical study reports, and Common Technical Documents (CTDs), they turn to professional medical writers for help in producing high-quality deliverables.

The future

As the Chinese government continues its support for drug development and strives to modernise its drug approval process, more products will be developed and more clinical trials will be conducted in China (Figure 2). This means that more professional medical writers will be needed.

Currently, most medical writers in China work for pharmaceutical companies, CROs, or large medical device companies. As the field continues to grow and as the first generation of medical writers gains more experience, some may choose to freelance or work as contractors. The idea of becoming a freelance medical writer may sound unimaginable to many Chinese medical writers right now, but in a few years it will not be.

Opportunities and challenges

When the CFDA begins to implement the CTD and require eCTD submissions for regulatory submissions in China, the need for medical writers experienced with CTDs will increase. However, few Chinese medical writers possess this skill. Many local Chinese medical writers therefore will face short-term challenges and a steep learning curve, but with adequate training and guidance, they should quickly be able to overcome the challenges. Once they have become proficient, they will be able to contribute more to submissions, whether China-specific or global.

The shortage of qualified medical writers provides many opportunities to experienced medical writers outside of China. Leading a medical writing team in China and providing training services to local medical writers are just two examples of these opportunities.

The evolving landscape of academic scientific publishing in China

Publication boom and misconduct

The number of scientific journal articles published by Chinese scholars has skyrocketed in the past decade.[6] This publication boom is the result of the Chinese government's enhanced support for science and research, coupled with the continued push for scientific publication by universities and research institutions (Figure 3). In addition to providing funding, many universities and research institutes offer a range of publication-related incentives, including name recognition, career advancement, and monetary awards, also known as cash-for-publication policies.[7]

However, with the push for more publications, especially in high-impact English journals, publication misconduct has become a problem.[8] Recent scandals have tarnished the integrity and reputation of Chinese research. These incidents have triggered prompt investigations and crackdowns from the Chinese government agencies, including the China Association for Science and Technology.[9] The investigations have exposed plagiarism, data falsification, authorship purchasing, manipulation of the peer-review process, and other kinds of misconduct. Determined to improve the integrity and reputation of Chinese research and scientific publishing, the China Association for Science and Technology has developed and is implementing a series of programmes to prevent fraud.[10, 11]

Challenges of scientific writing and publishing for Chinese scholars

Many researchers dread writing journal articles. If you ask, some of them might jokingly tell you that this is because they are pursuing science, not writing! Because of language barriers, writing in English adds another layer of challenges to many Chinese researchers.

To increase the likelihood of being published in English-language journals, many Chinese researchers seek editorial assistance from individual editors or editorial agencies. This has fuelled the increase in the number of editorial service providers in China. How many editing companies are operating in China is unknown, although a recent statement by the Alliance for Scientific Editing in China suggests that close to a thousand companies offer English writing and editing services to Chinese scholars.[12] Only a handful of these, however, are believed to be providing transparent and ethical services.

Challenges and opportunities for editorial service providers

Research and publication misconduct by some researchers in China has tarnished the image and

reputation of all of the editorial service providers. Researchers are frequently unfamiliar with guidelines on publication ethics, and may confuse legitimate and ethical medical writing services with spurious and improper services. As a result, many Chinese researchers hesitate to admit and acknowledge medical writing and editing support.

Despite research misconduct and publication-related scandals, the demand for legitimate medical writing and editing services will continue to remain high in China. The challenge facing providers is to deliver satisfactory services while protecting their reputations and receiving deserved recognition for their work.

The Chinese government is making great efforts to enhance research integrity in China.[13] Many leading Chinese researchers and government officials fully understand the importance of research and publication integrity and deeply care about their reputation. Through carefully planned educational programmes, updated publication guidelines, and enhanced government regulations, the quality of scientific publishing in China will improve, although it will take time.

Companies providing ethical and quality medical writing and editing services will need to make great efforts to distance themselves from the so-called "paper brokers"[8] and to maintain high ethical standards. When necessary, they will need to educate the researchers they serve and encourage them to follow the guidelines of international journals, such as the guidelines of the International Committee of Medical Journal Editors.[14] Building a transparent, ethical, and trustworthy relationship between legitimate editorial service providers and Chinese researchers will benefit all parties.

Summary

With the Chinese government's continued support for drug development and its determination to modernise its drug approval process, the Chinese pharmaceutical industry and the regulatory writing profession will continue to grow. Experienced medical writers who are familiar with the CTD format and who can both write well in English and understand Chinese will be of great value to pharmaceutical companies interested in accessing the Chinese market.

At the same time, the biomedical publishing industry will continue to grow in China. Recent scandals have caused concerns about the quality of scientific research conducted in China, but with enhanced regulation and extensive education, the situation will gradually improve. Ethical and high-quality medical writing and editing support is and will continue to be in high demand.

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Conflicts of interest

The author works with clients in the global pharmaceutical and healthcare industries.

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