

Preface

Since its opening in the early 1980's, China's pharmaceutical market has been burgeoning at a breathtaking rate. According to the China Pharmaceutical Market Report (2012), it has been and continues to undergo rapid expansion and intense market competition. An aging population contributes to the increase in the potential demand for drugs. This, coupled with an elevated level of purchasing power brought by economic development, is the driving force of pharmaceutical market expansion. Between 2005 and 2010, the integrated Chinese pharmaceutical market annual growth rate went over 20%. In 2012, the market scale reached 926.1 billion RMB (~\$ 150 billion). Looking ahead to 2020, the market will continue its rapid expansion with an average rate of 12%. In 2013 Chinese pharmaceutical market size exceeded 1 trillion RMB (~\$ 161 billion). In 2019, Chinese pharmaceutical market size is predicted to exceed 2 trillion RMB (~\$ 322 billion). In 2020, the scale will reach 2.3 trillion RMB (~\$ 483 billion). Unsurprisingly over the years, then, more and more foreign companies have entered China's market. Met with this and the increased demand for drugs, domestic Chinese pharmaceutical companies have synchronized their expansion. The result has been a trend towards foreign-funded enterprises in the pharmaceutical market. According to the marketing sharing and sales data of 2011, the top five companies in China are all foreign pharmaceutical enterprises.

However, while Chinese pharmaceutical regulations are indeed growing more mature with the market, there are still myriad differences between China's drug management law, regulations, and procedure and those of the Western world. To bridge these differences, many private consulting companies have been established, but with varied levels of success, and all bearing varied and faulty interpretations of the same regulations. To solve these issues, these consulting companies usually overemphasize their public relations, personal connections, and their strategies that limit equal opportunity in the market and in fact contradict Western common practice and basic law, such as the Sunshine Act. Ultimately, language barriers, misinterpretation of guidelines, and a lack of systematic educational materials have hindered many endeavors to effectively engage in and introduce new and needed drugs to the Chinese pharmaceutical market.

To elucidate these misunderstandings, the authors, together with the industry and government experts who have worked many years in the field of medicinal product development, have put together this guide to approaching and engaging with the Chinese market. As explained in the US FDA or other regulatory agencies' websites, all text and graphics regarding regulations are in the public domain—not copyrighted—and can be used freely. In contrast, there are different translated Chinese regulations and guidelines from various sources due to unknown reasons. Unfortunately, none of them are free of mistakes. The authors made corrections and modifications, and added some interpretations in reference to those publications in public domains, but strongly suggest that the readers check the original Chinese FDA's documents through the provided link if an uncertainty arises. The authors also cannot guarantee that the content and the opinions are totally error-free and accepted by all parties. Thus, in case of disagreement, the official adopted text in Chinese will always be the most authoritative source. This book aims to clarify the distinctions between Western and Chinese markets, taking the reader step-by-step through new drug development for Western companies hoping to expand into the Chinese market, running the gamut from the initial preparation phase to marketing approval abroad. The authors hope this book can help bridge the gap between languages and cultures, tackle unmet medical needs, and achieve a win-win outcome for not only pharmaceutical companies, but also patients and a larger society.

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Approaching China's Pharmaceutical Market

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