



Part I of a 2-Part Series: Urgent Issues Related to the Chinese Pharmacopoeia 2015

December 1, 2015 is the official implementation date for the Pharmacopoeia of the People's Republic of China 2015, also known as the Chinese Pharmacopoeia 2015 or ChP 2015. With all the efforts underway to harmonize monographs and other requirements among the major global pharmacopoeias (the United States Pharmacopoeia (USP), European Pharmacopoeia (EP), and Japanese Pharmacopoeia (JP)), one might assume that the latest version of the pharmacopoeia of the world's second largest economy, the ChP 2015, would also be included, but this is not necessarily the case.

Although there is no "official" English version of the ChP 2015 currently available, a legitimate translated version of it is expected to be available around March 2016 through USP. Those in the US excipient industry who have seen privately-commissioned legitimate translations of the official Chinese document are very concerned about both the test methods and specifications in a number of the monographs and predict that many heretofore "global" materials will not comply. Several companies have been working with IPEC China on translations of some of the monographs for many commonly used excipients, and concerns have been developing as the differences between the ChP 2015 requirements have been identified.

Previously, excipient, API, and finished dosage form (FDF) suppliers needed to comply with the ChP 2015 only if the excipients were to be used in drug products produced within China for the Chinese market. Excipients used in drugs produced outside of China which were imported into China were not required to meet the ChP requirements if other specifications, such as USP, NF, PhEur, etc. were utilized in their Import Drug License (IDL). New regulations recently published in China related to ChP 2015 have changed that – now any drug product and drug ingredient (excipient and/or API) intended for marketing in China (including those manufactured and imported from other countries) will need to comply with ChP 2015 requirements or use ingredients which comply with ChP 2015 requirements.

One of the key dilemmas of this situation is that although excipient suppliers are being asked by global pharmaceutical companies to provide excipients which comply with ChP 2015 by December 1, 2015, as mentioned above, a publicly-available reputable English version will not be available until March 2016. In addition, there has been very little notice of the changes throughout the industry so far, which will probably result in a number of materials being non-compliant or the status will be unknown.

The Chinese Pharmacopoeia Commission (ChPC) which issues the ChP 2015, has thus far been unwilling to make changes to ChP 2015, even for the purpose of harmonization with its other major pharmacopoeial counterparts. It is instead requiring scientific or other data to justify why such changes should be made and why existing global excipients cannot meet the requirements in ChP 2015. They argue that in many cases, Chinese suppliers can already comply with the

monographs in ChP 2015 and that they have concerns about possible adulteration if limits are expanded to match those in some of the other pharmacopoeias. Based on what initial investigations have already shown, it is feared that the Chinese suppliers who may meet ChP 2015 would not have adequate capacity to assume the entire Chinese demand. In addition, there are many excipients where there may not even be a Chinese supplier of significant volumes of material needed for commercial use. If technical issues and differences exist in ChP 2015 compared to the other major pharmacopoeias, it is possible that drug shortages may result or major pharmaceutical companies may not be in compliance with the new requirements.

Failure to comply with ChP 2015 could also result in delays (possibly months long) in clearing Chinese Customs if excipient manufacturers attempt to ship products without ChP 2015 designation into the country in December and beyond.

So what should excipient makers and users (FDF manufacturers) do?

- Stay tuned to the “IPEC Insider”. The ChPC Science Annual Meeting was held during the week of 21-Sept-2015. All the major global pharmacopoeial organizations participated. IPEC-Americas and the R&D-based Pharmaceutical Association Committee (RDPAC, a Chinese non-profit organization made up of 39 member companies with pharmaceutical R&D capability), who have similar concerns regarding the lack of harmonization with other pharmacopoeias, presented their arguments at the open session for the need for global harmonization of excipient monographs. IPEC-Americas and IPEC China representatives met with key ChP directors on September 24th to discuss the issues of concern to IPEC members and possible pathways forward. The results of the meeting are detailed in “*Part 2 of a 2 Part Series, IPEC-Americas Presentation at ChP Scientific Meeting In Suzhou, China on Sept. 24th*” in this edition of the Insider.
- If your company’s products comply with the ChP 2015, you should make sure that you designate its compliance (“ChP”) on the labeling.
- If your company’s products do not comply, you should submit a request for revision of the monograph by 1-Dec-2015 and be sure to include the impact (e.g., shortages due to lack of availability, a large number of FDFs affected, etc.) in your application. IPEC-Americas and IPEC China are collaborating on a template form that can be used to request revisions directly to ChP management. This request for revision process has been set up with ChP. Details on the process to be used will be provided to interested parties by IPEC-Americas.
- If you are not sure whether your company’s products comply, a prudent course of action would be to commission a translation of the monographs of interest, then follow the appropriate step above depending on the outcome.
- In the above two cases, excipient manufacturers and users (FDF manufacturers) should be communicating with each other regarding this issue as it is not practical nor helpful for users to simply demand that makers comply. In many cases, it will not be possible for many common excipients to meet the ChP 2015 requirements unless the monographs are revised.

While IPEC-Americas is not optimistic that ChPC will agree to a wholesale postponement of ChP 2015, we have been able to get ChPC to agree to a mechanism for makers and users to

apply for expedited revisions on a case-by-case basis. The details of this process will be shared with IPEC-Americas members in a webex meeting planned for October 8th.

Free Webex Presentation on ChP 2015 Revision Process for Urgent Changes Needed to Excipient Monographs

Date/Time: Thursday October 8, 2015 11:00AM-1:00PM EDT

Purpose/Objective: (Offered free as a member benefit): To inform excipient manufacturers and users what they need to do to quickly request revisions to specific Chinese Pharmacopeia (ChP) Excipient monographs where there are major technical problems with the test methods or limits that will prevent major excipients used in the market globally from meeting the ChP 2015 requirements. These requirements will become official on December 1, 2015 and will apply to excipients used in drugs that are made in China for use in China as well as imported drugs for the Chinese market.

A number of excipients which are currently used extensively in drugs marketed in China have already been identified which cannot meet the current ChP 2015 requirements. This could have significant compliance implications or impact on drug availability within China if revisions cannot be quickly made. A mechanism has been established for making these revision requests directly to ChP management for urgent consideration. Strong arguments with supporting data will be needed to convince ChP to make these revisions. This Webex meeting will provide guidance to IPEC members on what should be done immediately where these technical issues exist. Anyone involved with excipients used in China (Makers, Users and Distributors) should participate in this Webex meeting.

[Register](#)

Stay tuned!