Globalisation has facilitated greater international harmonisation and standardisation of quality standards, which in turn has impacted on pharmacopoeias. Historically, general chapters were developed based on input from local regions with little concern for global consequences. This often led to the development of similar, but unidentical tests, for example, Residue on Ignition (USP <281>) versus Sulphated Ash (Ph.Eur., 20414; JP, 2.4.44). Similarly, pharmacopoeial monographs of active pharmaceutical ingredients (APIs) were developed primarily based on the input of the innovator and single sources of the API. In contrast, today's monographs must reflect multi-source APIs from many generic suppliers, typically from India and China, rather than from Western Europe and the United States. Consequently, the test methods must be cheap, globally available and state-of-the-art, but selective and robust – often a significant challenge.

Pharmacopoeial harmonisation of general chapters and specific monographs was always going to be challenging; however, progress has generally been extremely slow. The main reason is that the seven-stage harmonisation process, whereby regional perspectives need to be discussed and agreed, is a lengthy and iterative one. Some of the inherent challenges were differences in interpretation, legal status and cultural perspectives, which were always likely to arise given the very different status of pharmacopoeias, that is, USP (non-governmental), JP (governmental) and Ph. Eur. (pan-governmental).

The majority of the general chapters that reached stage six regional consensus agreement are not totally harmonised (as per ICH Q4B definition), most have been coordinated by attributes. Although the primary reason for harmonisation – supporting the implementation of the ICH Q6 guidelines – was achieved, the lack of meaningful harmonisation has still resulted in extra testing by industry. Additionally, the US Food and Drug Administration indicated in the ICH Q7 guideline that harmonisation has meaningfully reduced costs or time to market.

Only two thirds of the general chapters, and just over half of the specific monographs that were under consideration, were meaningfully harmonised as part of this initiative (where harmonised is stage five or beyond, and stage five is defined as consensus). This has reflected in ‘black diamond’ text in all general chapters, reflecting regional differences. With such caveats in place, it is difficult to claim that this initiative has meaningfully reduced costs or time to market.

References

10. USP, 2015b. Propylene glycol monograph. USP38, 5865-5866