United in diversity

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While the exact definition of what comprises the Asia Pacific region tends to differ depending on context, it is an oft-used cliché that the approximately 50 nations comprising the region that spans South Asia, East Asia, Southeast Asia, and Oceania are "united in their diversity". Beyond this truism, however, is the fact that many of these countries are viewed as emerging markets that are experiencing rapid growth and present significant opportunities. Countries that are expected to experience double-digit levels growth over the coming few years include Vietnam, China, Sri Lanka, Myanmar and Bangladesh.

Indeed, Asia Pacific is the third largest pharmaceutical market in the world after North America and Europe. A steady rise in healthcare expenditure across the region, fueled by a rising middle-class, ageing population combined with the expiry of a number of patented drugs has meant that generics have proven to be a central driving force. Across the region as a whole, combined sales of prescription drugs and over-the-counter (OTC) medicines are forecast to increase from approximately $275 billion in 2013 to approximately $385 billion in 2018, representing a five-year compound annual growth of 7%.

While the diverse cultural nature and economic maturity of Asia Pacific's markets pose challenges, substantial gains have been made by the Association of Southern Asian Nations (ASEAN), a collaboration of ten nations with a combined population of 621 million. To this end, ASEAN has made significant progress towards harmonisation through technical cooperation between member nations and implementation of guidelines and mutual recognition agreements in order to build a common platform for drug registration. The numerous challenges and opportunities that the ASEAN emerging regulatory landscapes present to us is reviewed in this edition of our journal, providing a comprehensive overview of documentation preparation, submission and post-approval requirements across this harmonised regulatory framework.

In contrast to the emerging and developing markets of the region, Japan, South Korea, Australia and New Zealand represent developed, economically mature markets with established regulatory frameworks. The Australian clinical landscape is also placed under the spotlight this month, with recent developments offering pharmaceutical manufacturers the opportunity to reach patients sooner and at lower cost than in many other Western countries, with the additional draw of significant tax incentives. A further article focuses on the clinical requirements of the East Asia markets of China, South Korea and Japan, which highlights the opportunities for collaboration that lie therein.

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Outside of this month's focus topic, we have in-depth coverage of the Annual European Medicines Agency's Review of the Year and Outlook for 2016 (held on 19–20 November 2015). This meeting report provides insights into a range of topics including the development and innovation of new medicines, post-approval activities, the new EU Clinical Regulation and the involvement of patients and healthcare providers in the work of EMA and its committees. Presentations were given by an international panel of speakers from a variety of regulatory agencies, as well as industry experts.

Meanwhile, an interview with Heidi C Marchand (Assistant Commissioner of Health and Constituent Affairs, FDA) provides a fascinating glimpse into the vital role that she performs, building trusted relationships with the FDA's diversity of stakeholders on public health issues.

Pharmaceutical companies looking to maximise their return on investment are increasingly considering the region in their portfolios outside of the more mature markets of Australia, New Zealand and Japan, but only by understanding both the similarities and differences in regulatory processes across all individual markets can a truly global expansion strategy be successful.