New dynamics in North America

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Since President Trump signed PDUFA VI (also known as the Food and Drug Administration Reauthorization Act, or FDARA) in 2017, the US regulatory environment has continued to evolve and adapt to a changing world. The FDA's role in managing the opioid epidemic in the US continues to be defined, and the rollout is ongoing for the Oncology Center of Excellence to manage review and administrative procedures across different parts of the FDA, which are involved in regulating oncology products.

Additionally, progress continues on the goals that were agreed as part of PDUFA VI, including the future development of guidance documents for patient-focused drug development (described in more detail in this issue), real world evidence, several combination product policies (patient-oriented labelling and bridging studies), and communication best practices. Furthermore, the FDA will report on its assessments of previous goal agreements, including Sentinel and postmarketing surveillance, paediatrics, FDA resourcing, the use of benefit–risk frameworks, and the priority review voucher programmes.

Planning for PDUFA VII has also commenced, with the trade associations beginning to collect input from stakeholders, before initiating discussions with the FDA on the agreed-upon PDUFA goals. These will then become part of the updated legislative documents, for the US President's signature in 2022.

In addition to the PDUFA VII planning activities, we continue to see improvements in how the FDA works with regulatory authorities outside the US in terms of work-sharing agreements, Good Manufacturing Practice (GMP) inspections, Memoranda of Understanding, and scientific meetings. New trade agreements between the US and other countries (for example, the recently signed US/Mexico/Canada agreement) are sure to bring new considerations to regulatory strategies. The continued evolution of the European environment – especially Brexit, and how the UK Medicines and Healthcare products Regulatory Agency will regulate UK medicines after the UK leaves the EU – will certainly be important for US regulatory professionals to keep in mind, as these changes may impact regulatory strategies for clinical study sites, submission planning and selection of an optimal source country for certificates of pharmaceutical product (CPP).

As the world continues to get smaller, the North American regulatory environment must continue to evolve, and new norms will result from that evolution. As an example, we have started to see agencies like COFEPRIS in Mexico open up new regulatory pathway opportunities, such as conditional approvals, which can lead to the first approval of a regulatory submission in the world, ahead of the US and Europe, thereby accelerating access to new, life-saving therapies by patients who previously would have waited years after approvals by the US or Europe. These new approaches and the amplification of the patient voice in drug development are exciting regulatory science innovations for patients in Mexico.

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Health Canada is also undergoing transformation. The Regulatory Review of Drugs and Devices (R2D2) initiative has three key areas of focus: (1) expanded collaboration with health partners (including work-sharing agreements with Australia, Switzerland and Singapore); (2) more timely access to drugs and devices; and (3) enhanced use of real world evidence. The agency is currently collecting stakeholder feedback on a number of initiatives, both in-person and online, with updates on the status of the consultations available online. The consultation process is targeted for completion in 2021 and should result in improved access, appropriate use and affordability of new products to patients in Canada.

With increased emphasis on patient-focused outcomes, affordability and increased access to new medicines, the North America regulatory environment remains dynamic and exciting. In addition to pressure on timelines, agencies are now looking at different ways to cope with new types of data, different stakeholders, and an evolving landscape so as to keep up with the science, respond to unmet medical needs, and optimise patient care.