Change? Or just more catching up?

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It's been exactly a year since our last North America focus issue – and what a year it's been. Not only have we seen a new US President and change in administration, but there is now a new FDA Commissioner and a renewed focus on all things innovative. In the last year alone, we've seen the approval of Kymriah, a genetically-modified autologous T-cell immunotherapy – the first gene therapy product to be approved in the US (and the world's first approved chimeric antigen receptor T cell [CAR-T] product). In addition, new guidelines on biosimilars, biomarker qualification and structured benefit–risk assessments are pushing innovation forward at the Agency. Further changes will also be afoot in due course under PDUFA VI, which will see increased leverage of real world data/evidence (RWD/RWE), more patient involvement in FDA activities, longer preparation times for some Agency meetings, and mandatory paediatric evaluations. However, many of these measures are similar to provisions that have been in place for some time in other territories such as the EU, so perhaps it could be argued that the FDA, rather than leading the field, is only now joining it?

This harmonisation is evident in our first focus article, in which we hear about the regulation and development of mobile health (m-Health). The authors cite international standards, such as IEC 62304 – medical device software – software life cycle processes, that have been harmonised by the US and the EU and therefore can to be used to benchmark regulatory requirements for both markets. In addition, in September, as part of its Digital Health Innovation Action Plan, the FDA progressed a first-of-its kind digital health software pre-certification pilot programme intended to revolutionise digital health regulation in the US. Nine companies, all of whom are experienced medical device or technology developers currently planning or developing digital health tools (software product(s)), will undergo systems reviews by the FDA for software design, validation and maintenance with a view to being "pre-certified". The ultimate aim is to see if pre-certification enables companies to submit less information to the FDA before the digital health tool is marketed (or even if a premarket review can be avoided in some cases). This is a fascinating and rapidly developing area, and is not without its challenges, so it will be interesting to see the outcome and whether, if successful, similar approaches are rolled out in other regions.

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The other two focus articles both highlight that innovation in North America is not limited to the US. For the veterinary medicines sector, the regulation of animal health products in Canada is extensively covered in the first article. In the second, many of you will no doubt applaud the welcome return of *Maple Leaf News,* with its informative roundup of hot topics in the Canadian regulatory arena. We also eagerly await the outcome of the ongoing work by Health Canada to introduce amendments to the regulations to allow provision for an orphan drug scheme – this has been discussed on and off for some years, so we hope that it comes to fruition in the mid-term.

Coming full circle back to innovation, Dr Martina Schüssler-Lenz summarises the work of the Committee for Advanced Therapies (CAT) in pushing boundaries and responding to advances in technology. Maybe the November implementation of the EMA-FDA mutual recognition of good manufacturing practice (GMP) inspections of medicines manufacturers is the first of many formally and publicly-recognised interactions between the two agencies?

It's always been clear that the EMA and FDA often and increasingly share information in an informal manner, but formal interactions and close working for individual applications or products have not formed part of the arrangements. Who knows – maybe, one day, we will have a single global regulatory agency? It's probably a very long time away – and may never happen – but we are increasingly moving towards harmonisation on a number of levels.