LIFE SCIENCES INDEX 2026 SPOTLIGHT ON:

Regulation

The global life sciences sector is experiencing severe turbulence. In the EU, chronic financial shortages are curbing public healthcare spending. US tariffs and the government's repeated announcements about applying a "most favoured nation clause" for drug pricing are exacerbating the need for competitiveness. Businesses are being forced to accelerate key company decisions to avoid being left behind.

The EU's competitiveness gap is widening compared to other global players – notably China, which has introduced several regulatory changes to foster innovation.

ACT-EU is delivering good progress (see my thoughts on clinical trial regulations in **Chapter One**: Fostering Innovation and Growth of this Index). And the long-awaited European pharmaceutical legislation reform seems close to approval.

Contrary to the Commission's original proposal in April 2023, both the European Parliament and Council have resisted radical changes to regulatory data protection periods. Instead they've chosen to refine existing terms in the pharma law reform approved on 11 December, after 32 months of negotiations.

Other controversial issues have finally been resolved. For example, the transferable exclusivity voucher incentive for new antibiotics, an unprecedented measure from a global regulatory perspective. There are conditions to obtain the voucher, and no doubt there will be practical difficulties in implementing this new measure. But the co-legislators should be commended for approving a tangible incentive to R&D investments on new antimicrobials.

While the US administration has decided to change the FDA's organisation and governance, the members of the European Medicines Regulatory Network (ie the Commission, member states and the EMA) have increased their cooperation in a quite stable environment.

The EU's use of evidence-generating approaches – such as extrapolation, modelling and simulation – is expected to increase, driven in part by the growing availability of real-world data through platforms like DARWIN EU® (Data Analysis and Real World Interrogation Network). In 2025, the EMA initiated 100 studies through DARWIN EU. The platform acts as a pathfinder for the European Health Data Space (EHDS), demonstrating the benefits that regulators get when accessing and analysing large healthcare datasets.

Both the FDA and EMA are enhancing their efforts to keep pace with the use of AI in pharma. AI is predicting protein folding, modelling pharmacodynamics and pharmacokinetics in silico. It's being studied to identify alternatives to animal testing and via Large Language Models. And it's transforming unstructured data into structured data and supporting regulatory reviews.

AI is becoming an integral component in medical devices. Recently the EMA/CHMP issued a qualification opinion for an AI-based measurement of non-alcoholic steatohepatitis (AIM-NASH). It analyses liver biopsy images and quantifies histological features to determine disease activity in NASH/MASH. Innovators have to ensure they're using fit-for-purpose algorithms and datasets in accordance with current ethical, technical, scientific and regulatory standards.

Access to medicines across the EU still varies widely. With the EU regulation on HTA, in parallel with the EMA's evaluation of the marketing authorisation application, new drugs will now undergo a Joint Clinical Assessment (JCA). A JCA won't replace national decisions on pricing and reimbursement, but it's intended to help member states make decisions, facilitating faster and more uniform access to innovation in the EU.

A sort of "regulatory competition fever" seems to have hit regulatory authorities, each striving to make their country more attractive for R&D investments. The European Commission has just launched a Biotech Act aimed at boosting innovation, helping small and medium enterprises to find new capital for their activities, and streamlining clinical trials and regulatory paths. And the FDA has just announced that they'll no longer require comparative efficacy studies for biosimilars, replaced by comparative analytical assessments. This will significantly reduce the time and effort manufacturers spend on placing their biosimilars on the US market.

Life sciences companies should keep a close eye on these global political and legislative developments. They're an opportunity for growth and may at least partially compensate for the lost income and capitalisation over the last three years.

Stefano Marino
DLA Piper Senior Consultant and Former Head of Legal, European Medicines Agency (EMA)
stefano.marino@dlapiper.com

dlapiper.com