Interesting times ahead

BOB CLAY, TOPRA PRESIDENT

The regulation of medicines and medical devices in Europe faces unprecedented challenges over the next few years. I hope that regulatory professionals across all sectors will rise to the occasion; perhaps joining the Board is your chance?

When I decided to seek election to the TOPRA Board of Directors, it was in the hope that I could contribute to the leadership of a profession I joined more than 30 years ago. I did not imagine that my year as President in 2017 would be at such a critical period for the regulation of healthcare: after two UK General Elections and a Referendum we stand at the edge of an unexplored forest.

As a pharmaceutical reviewer at the UK regulatory authority in the 1980s, we had a single EU concertation procedure intended for a limited range of biotech products and rarely used. When I left in 1990, I could not have imagined that within five years we would have two effective, collaborative registration procedures leading to an EU-wide approval of new therapeutics. Establishing the EMA and collaboration between member state agencies has led to a regulatory system that facilitates the engagement of resources and expertise from not only the EU, but also Norway and Iceland. This cooperation spans virtually every aspect of the development and marketing of medicines: encouraging innovation, supporting small companies and academics, development and introduction of new technologies, modern risk management and pharmacovigilance, and the development of medicines for children and rare diseases.

The opening discussions between the UK and EU-27 suggest that this uncertainty will take time to resolve, particularly given that medicines regulation is a singular element of a complex political rearrangement. However, they did indicate that the location of the EMA would be decided in November. The EMA has highlighted some of the challenges that face marketing authorisation holders if the UK is no longer a member of the EU. The loss of UK expertise and resources in the system and the disruption created by a move of the EMA are obvious risks, but the deep integration of the current system will present other challenges – for example, the regulation of clinical trials and post-market risk management.

The EMA and the MHRA have both benefited from a high degree of independence as agencies and have been able to develop regulatory systems based on common legislation to the benefit of the main stakeholders. We can only hope that many of the benefits of cooperation gained over the past 25 years will not be lost. The changes that occur will be outside of our control, but how we respond and bring our professional experience to address the challenges is not!

I hope that TOPRA can continue to develop across Europe; becoming a Board member is an important representation of the diversity of our membership and I hope that many nominations will be received to ensure that the future Board continues to have members from regulatory agencies, industry and different countries. If you are considering putting yourself forward please see page 3 for more details. If you are not ready yet – there are many other opportunities to contribute.