Essential insights from the TOPRA **European regulatory fora of the year**

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This year's TOPRA Annual Symposium was held in Berlin in October, in conjunction with the Federal Institute for Drugs and Medical Devices (BfArM) and the Federal Office of Consumer Protection and Food Safety (BVL). The Annual Symposium is an essential meeting for regulatory professionals to gain both an understanding of current and evolving regulatory requirements, as well as insights into future plans for regulations. This year's meeting was widely attended by regulators and industry alike, providing a forum for collaboration and interaction that we hope continues to drive the "ideal" of both parties seeing each other as partners in development, improving the efficiency of delivery of safe and effective healthcare options to patients. We are very grateful to our meeting reporters for the comprehensive and excellent quality coverage in the pages of this edition of *Regulatory Rapporteur*.

Now in its twelfth year, the Annual Symposium is actually a bit of a misnomer, as it comprises four symposia: human pharmaceuticals, medical devices, veterinary medicines, and SME Day for small and medium-sized enterprises (SMEs).

In the symposium's opening annual lecture, Prof Dr med Karl Broich, President of Germany's regulatory agency, BfArM, focused on personalised medicine and the fast-paced technological development of next generation sequencing (NGS). The application of NGS connected with the evolving area of "big data" is seen as an essential area for future medicines development and, in particular, in therapy areas such as oncology and neurology.

Symposium sessions reported in this edition cover a raft of topical subjects, including accelerating drug development and patient access; progress towards implementation of the EU Clinical Trials Regulation; scientific and health technology assessment advice; the globalisation of pharmaceutical regulations; challenges remaining for mutual recognition and decentralised procedures; biosimilar medicines; consideration of the Pharmacovigilance Regulation in the three years since its introduction; and the availability of medicines.

New legislation was a key theme of several presentations. Recognising that those interested in human medicinal products are awaiting the implementation of the EU Clinical Trial Regulation, while devices regulatory professionals are anticipating the nature of ongoing revisions to EU medical device legislation, delegates were offered chapter and verse of current and future initiatives.

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With the growing co-development of drug-device combination products, one presentation covered regulatory challenges faced and the importance of usability and human factor testing in this product class. Among other highlights in our devices coverage, we hear from UK and German competent authorities on the subject of clinical investigations and evaluations.

There is change afoot, too, in the veterinary medicines sector. While new legislation is further along the horizon than the other sectors, with implementation foreseen during the summer of 2019, the legislative process for this sector has already begun. With this in mind, the veterinary medicines symposium discussed the key objectives of the new legislation, and how these could best be achieved. Other sessions covered issues surrounding antimicrobial resistance, animal welfare and regulatory hurdles for vaccines, among other topics.

At the SME Day, delegates were given valuable guidance by the EMA's SME Office, and an industry view highlighted the huge benefits of scientific advice from both the EMA and at a national level.

In keeping with our German emphasis this month, an interview with Professor Dr Klaus Cichutek, Head of the Paul-Ehrlich-Institut (PEI) provided key insights into the vital role of the PEI, including an overview of some of the key challenges faced by the agency, as well its recent successes.

There is little doubt of the breadth and depth of regulatory information provided at the TOPRA Annual Symposium from the broad overview of topics introduced in this editorial. For those readers who were not fortunate enough to attend, we hope that you enjoy this edition's account of key developments in our field, and that it stimulates your interest to attend the symposium in future years.