Patient engagement or involvement?

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Involving patients in developing new therapeutics should be an integral part of our process, but to do so we need to adopt new approaches and understanding. How does this affect us as regulatory professionals?

Over the past few weeks, I have attended two meetings involving patients contributing to medicines development. These experiences caused me to reflect on not only on how far we have come so far, but also on the path ahead for our profession. As a pharmacist, the interface with the patient is a key part of the role and early in my career we were trained in "patient counselling": the primary objective was to ensure that patients understood their medicines and were likely to take them appropriately. We also wanted to understand if there were other concerns or side-effects.

In last month's issue of *InTouch*, I highlighted the annual meeting of the Critical Path to TB Drug Regimens (CPTR). There were several patients involved in the meeting, giving presentations and participating in panels, sharing their experience of care pathways and the impact of drug toxicity, including hearing and vision loss. These presentations made a huge impact on the audience and as with similar meetings I have attended they are highly motivational for those involved in the endeavour of developing new medicines.

The meeting that inspired this editorial was a symposium organised by the **NEC Society**. Necrotizing enterocolitis (NEC) is a devastating intestinal disease impacting premature infants, it is life-threatening and survivors may be left with lifelong neurological and gastrointestinal complications. The meeting was a collaboration between affected families, clinicians and researchers to address the issues across the whole spectrum of care, prevention and treatment including the understanding of the disease processes. Although the NEC Society is not unique, in my view it represents an example of patient involvement at the highest level; where patients are involved in developing an understanding of disease, care pathways, advocacy for investment, creating research collaborations and bringing together stakeholders to establish priorities.

There is an increasing literature base considering approaches to patient centricity or patient-focused drug development, and both pharmaceutical companies and regulators are devoting increasing resources in this area. In the development arena, this includes involvement of patients in study and programme design and developing more patient relevant clinical endpoints. Both the US FDA and the EMA have active programmes to involve patients: the FDA has included patient representatives in advisory committees and a range of consultations, while the EMA has included patient representatives in several committees and in some CHMP benefit–risk discussions.

While regulatory professionals and TOPRA are involved in these developments and they influence many of our programmes, in my view if we want to lead in this area it is time for a more explicit approach. I would welcome views from members on the topics highlighted and how TOPRA should respond.