Regulation and global health

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Our recent Annual Symposium, held in London in partnership with the MHRA and VMD, was an inspiring event with a theme of "Global regulatory approaches to improve healthcare"

Before addressing this month's theme, I would like to thank all those involved in the Symposium which represents a unique collaboration between TOPRA and the host country national regulators. Thank you to the TOPRA staff, the Symposium working party, speakers, exhibitors, delegates, and particularly to our hosts and the many representatives of the MHRA, VMD and other regulators for their contributions.

Global health is a theme that I have highlighted in several previous editorials and in my view, it is one of the most important aspects of our contribution as regulatory professionals. We frequently hear the call for reduced regulatory burden and simplification, in the wider press and political sphere; we do not often hear about the benefits of regulation, except after crises attributed to the failure of regulators or regulations.

The importance of good regulation in the promotion of global health was addressed by Dr Murray "Mac" Lumpkin who opened the Symposium with the Annual Lecture. He highlighted the imbalances between developing medicines based on the burden of diseases against the commercial drivers for an appropriate return on investment. He used a series of alternative world maps to highlight the changing shape of the global population and the burden of certain diseases, including Malaria, TB and HIV. Dr Lumpkin described "the good, the bad, and the ugly" in the context of medicinal product registration: the "good" ie, regulation done well which facilitates access and positive impact of medical innovation; the "bad" which delays access and has a negative impact on health and the economic wellbeing of communities; and the "ugly" where regulation does not exist and patients are exploited in a "buyer beware" setting.

There have been many attempts to address these challenges supported by WHO, national regulators and foundations. These endeavours include approaches to regional regulatory collaboration, as highlighted in Africa by the regional cooperation groups and the potential development of an African Medicines Agency.

Another important approach has been the development of facilitated registration pathways, such as WHO prequalification and the EU Article 58 opinion.

Dr Lumpkin introduced the concept of "reliance" into the discussion, this is important because it moves our thinking beyond the common approach of "mutual recognition" – asking one regulator to accept the decision or standards of other bodies. The reliance approach would ensure that national regulators are able to benefit from the work undertaken by others, while building their own capabilities and retaining their accountabilities for regulation.

I have not done justice to our keynote speaker's presentation; but, I hope I have highlighted an inspiring aspect of our profession and that our individual contributions to the regulation of medicines should be for the "good" regulation. See you next year in Stockholm for the 2018 Symposium!