



The exhibit hall was a sort of spectacle for a student who has never attended any convention such as this. Although the exhibitors were not particularly looking for students and were more geared to selling their products or services, many of them were willing to help explain what their companies did and potential future opportunities in their company for PharmD professionals such as myself. The number of companies far exceeded my expectations and truly broadened my view beyond the “big name” companies that are always on the news. The SIAC luncheon and ongoing SIAC online communities are also quite valuable to both students and professionals. I look forward to interacting with professionals in my SIAC community to help establish my chosen career path.

The DIA Annual Meeting is something I would highly recommend to anyone even remotely considering a career path in pharma, and I look forward to learning and networking even more in the years to come. ●



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Medicines Agency, and the US FDA (Session 139). This panel discussion addressed some upcoming challenges and steps in regulatory cooperation as well various approaches the agencies employ to meet their domestically-focused mission in our increasingly global environment.

In April 2011, Health Canada updated user fees for its human drugs and medical devices

Session Report: DIA 2012 Regulatory Summit

What regulatory collaboration will look like as we go further into the 21st century was a primary focus at the DIA 2012 Annual Meeting, especially throughout *Regulatory Collaboration/ 21st Century Innovation: Views of the Heads of Health Canada, the European*

regulatory programs for the first time in 14 years, explained Paul Glover, MBA (Assistant Deputy Minister, Health Products & Food Branch, Health Canada). Previous funding levels made it difficult for the Agency to efficiently operate, and created numerous backlogs. Parliament, while approving this new fee structure, made it very clear that this structure came with the companion expectation that Health Canada would do a better job.

Health Canada's new operating environment is based on three basic priorities: **Remain true to the evidence** as a science-based regulatory Agency, and invest in scientific regulatory staff to keep abreast (if not ahead) of an industry that grows increasingly global and complicated; **deliver operational excellence**; and **embrace regulatory modernization** in Health Canada's transformation into an Agency that simultaneously reflects its national priorities and the interconnected global industry it regulates.



Executive Director of the European Medicines Agency, Dr. Guido Rasi spoke about facing some of these very same challenges such as clinical trials, supply shortages, personalized medicine, counterfeit medicine, and so on. Dr. Rasi used two key words to summarize the future of regulatory cooperation in our increasingly global environment: Trust and Role.

We must trust in each other as regulators, and even more trust is required when dealing with the results of clinical trials conducted in another country. It is clear that trust in regulators and industry have seriously declined. To overcome this decline will require new and improved ways of communication, transparency and even greater levels of industry-regulatory collaboration. Dr. Rasi also referenced the alarming and growing number of people who use unregulated substances because they trust what their neighbors tell them or what they read on the internet more than they trust regulatory or industry expertise. It is paramount that we all work together to restore the trust between consumers, industry and regulators, and thereby truly protect public health and safety.

When trying to define the regulators' role in our collaborative future, Dr. Rasi suggested the definition will be found in answers to such questions as: *Are we the gatekeeper or are we the enabler? What is the regulators' role in comparative effectiveness? Is industry ready to challenge us with other tools to assess their efforts to produce innovation?* Addressing these basic principles of trust and role, assured Dr. Rasi, will help move global regulatory collaboration forward.



Paul Glover of Health Canada, Margaret Hamburg of FDA, and Guido Rasi of EMA discuss regulatory collaboration at DIA 2012.

FDA Commissioner Dr. Margaret Hamburg added another word to Dr. Rasi's critical terms: Partnership. We live in a world where science is advancing rapidly in an increasingly globalized world. The FDA regulates products that come in whole or in part from more than 300,000 facilities in over 150 countries. At the same time, it is critically important that science remains the single most important tool in our regulatory processes. All these factors combine to demand that regulators are adequately positioned to address the challenges of today, tomorrow and the future. Trust and confidence form an important part of the foundation we need to introduce the changes that regulatory agencies need to accomplish their mission.

Over the past decade, numerous regulatory authorities have formed partnerships to share information through bilateral and multilateral agreements. They have also worked toward harmonization of standards as well as converging upon ways to approach problems with different international organizations. Even so, we cannot continue to do global work through this patchwork of formal and informal relationships. Institutions and systems must reflect the demands of globalization, Dr. Hamburg explained.

Industry, patients, consumers, healthcare providers, media, lawmakers and other critical stakeholders must all work together to advance new ways of thinking that reflect the light of these global challenges, the panel concluded. These new ways of thinking will benefit every nation because we will be regulating products that meet higher standards of safety, efficacy and quality. ●

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