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CPhI announces impact of change in global regulation on healthcare cost

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Two annual report experts, Dilip Shah nand Bikash Chatterjee review the impact of 'IPRs and trade agreements' and 'regulatory divergence' respectively, suggesting the implications of both could have profound impacts globally

CPhI Worldwide the world's largest pharma event taking place in Madrid (9-11, October 2018) and organized by UBM (part of Informa plc) has released the second part of its annual report, which evaluates the effects of regulatory divergence, trade agreements and IP rights over the next 5-years.

Two annual report experts, Dilip Shah, CEO of Vision Consulting Group, and Bikash Chatterjee, President and Chief Science Officer at Pharmatech Associates review the impact of 'IPRs and trade agreements' and 'regulatory divergence' respectively, suggesting the implications of both could have profound impacts globally.

Dilip Shah argues strongly in his paper that the global trend towards patent term restoration and extension will result in patients needing to wait an extra 5 or 10 years to access generic versions of medicines. In many cases Regional Comprehensive Economic Partnership (RCEP) texts seek to redefine the protection period to 20 years from the date of marketing approval.

"For example, 'Patent linkage' under Comprehensive and Progressive Trans-Pacific Partnership Agreement (CPTPP) will require [generic company] to gain consent from patent holder prior to use of data in (generic) marketing approval. CETA between the EU and Canada has similar patent restoration as does EU-Japan economic partnership agreement." commented Shah.

However, Shah believes this may, in fact, result in longer-term consequences for the industry with consumers and

governments ultimately forcing a fundamental reform of how medicines are reimbursed. Over the course of the next 5-years, he forecasts that healthcare costs could potentially rise globally by as much as $100bn. The implication for the patented pharma industry is that it is likely to come under sustained pressure in the medium term (5-10 years hence) to reduce prices.

Bikash Chatterjee in his paper on 'regulatory philosophy divergence and innovation convergence in the next decade' predicts China's rate of advancement is still accelerating and that we can very quickly expect full harmonization with ICH standards. The net result will be that China's overall standards will improve quickly and poor quality manufacturers will drop out of the market in the next two to three years.

Globally, he foresees that whilst regulators are actively diverging in their philosophies, technology and innovation is simultaneously converging – with frameworks grounded in scientific tools and analytical techniques. For example, process validation in the future will be completed for individual patients, not batches. CAR-T and NGS have opened a potential regulatory pathway for even 3-D bioprinting of organs to follow.

"We have seen ground-breaking drug therapies and diagnostics approved in the last five years that position regulatory bodies to embrace these new innovations. Whether risk is managed via enhanced control and oversight, such as with the EUs GDPR legislation, or is a by-product of intelligently gathered real-world data, as provided under the US's 21st Century Cures Act, the regulatory evaluation in each framework required to evaluate these new technologies will be grounded in today's scientific tools and analytic techniques.

Technology is playing an increasingly large role in improving rates of attrition. Over the next five years, big data will catalyse drug discovery with R&D leading to the quicker advancement of more targeted therapies"added Chatterjee.