Pharmaceutical Manufacturing and Supply-Chain Trends to 2020

A breach in the pharmaceutical supply chain is only the tip of the iceberg.

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Innovators (Big Pharma and biotech companies) are today a minority player supplying only about 20% of the world's medicines. At present, the vast majority of medicines are generic—the fruits of the best science of the 20th century can now be enjoyed for a few cents a pill.

Tax strategies were the one common manufacturing strategy of Big Pharma, and we can expect manufacturing outsourcing to be the next one. This will happen not only because of speed and the need to ramp-up production without capital expenditure, but also because new compounds have issues that can only be solved by complex manufacturing technologies. Today, no organisation can afford to have all the new tools and relevant competences in-house.

Competition and pressure on margins in generic drugs have caused the delocalisation of their manufacture. In the next decade, India and China will be the pharmacy to the world. The concern, however, is not around science and technology in manufacturing or capacity but in the absence of a culture that drives quality and compliance. Regulators are up-in-arms taking action, issuing warning letters, import alerts and fines to a large number of Indian firms, mostly because of data-integrity issues. But that is unlikely to solve the matter—real quality, like safety, requires the right tone at the top.

Another disconnect is in the standard setting process, which is still in the hands of Big Pharma even though the majority of pills are generic. The question is, are we at risk that the standard becomes disconnected from reality?

The complexity and porosity of the generic-drug supply chain and the cost of quality have created windows of opportunity for criminals. Falsified pharmaceuticals is the fastest growing pharma segment. Those purchasing their medicines from Internet pharmacies have a 96% probability of getting a wrong, illegal, product that is a threat to patient safety. And this problem is only the tip of the iceberg. When illegal APIs get into the legal supply chain, tragedies occur, for example, the hundreds of children who died as result of contaminated cough syrup in Haiti and Panama, and the case of more than one hundred Americans killed from contaminated heparin. Once inside the legal supply chain, nobody can differentiate between the good and bad medicines, unless the toxicity is acute and by then, it is already too late.

The armed robbery of trucks carrying palettes of pharmaceuticals (innovator as well as generic medicines) happens weekly in Brazil, Mexico and Italy as highlighted in supply-chain security meetings of Rx-360. A pharmaceutical warehouse theft now has the record for the largest goods theft at $70 million in one heist (1).

The Falsified Medicines Directive brought a major innovation. The "written confirmation" is the first example of a mechanism of true global regulator collaboration. Regulators are now watching each other's backs. However, if we want effective solutions and faster pace of progress, we will need tougher sanctions, such as criminal penalties for individuals. The deterrence of jail sentences and debarment of CEOs that do not do the right thing would serve patients well.

Reference

1. NBC News, Robbers take $70M in prescription drugs, Press Release, 16 March 2010. **PTE**