

## Columnists

Potent mix - Sam Porteous ( 30/07/2007)



### Sam Porteous

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Given the recent coverage of the impact of globalized sourcing patterns on food safety it will not be long before consumers and the groups that protect them will be taking a long look at what is inside their medicine cabinets, where it comes from and how it was made.

In many cases, the answers will not be comforting.

Many of the weaknesses of the current international import and sourcing regime exposed by recent food scandals - inadequate regulatory supervision in both source and importing countries as well as a "not my job" approach to quality control and safety issues among the relevant private sector actors, particularly middlemen, from both developing and developed economies - are set to emerge again.



Today, the market for active pharmaceutical ingredients - the chemical substances in medicines that make them work - is becoming increasingly globalized.

Analysts estimate up to 50 percent of active ingredients now being used in the United States to make pharmaceutical products are sourced from China and India. This figure is expected to hit 80 percent in 10 years.

Currently, APIs sourced from emerging economies tend to be used primarily by players in the fiercely price competitive generic drug industry.

However, this is set to change as many major pharmaceutical firms that have traditionally made most of their own APIs have recently outlined plans to outsource them - mostly from India and China.

But these two countries are not the problem. Both have several first rate active pharmaceutical ingredient manufacturers who meet or even exceed Western standards.

Outright criminals and counterfeiters who attempt to enter the global supply chain for pharmaceutical products are the real culprits.

And the current country-based regulatory system designed in an era when most of these ingredients were sourced locally is proving wholly inadequate to deter these wrongdoers.

The US Food and Drug Administration has readily admitted it does not have the budget to investigate all the foreign suppliers it would like to visit.

Furthermore, the resources the FDA does have seem to be deployed to address the problems of an earlier age.

Just this past year over 1,200 random FDA inspection visits were made to relatively low-risk US manufacturers while in the same time period only 32 visits were made to Indian manufacturers and just 15 visits were made to Chinese facilities.

In addition, unlike the US manufacturers, the foreign facilities were provided advance notice prior to the FDA visit.

Another nagging problem with APIs is they tend in many instances to be moved around the planet through myriad middlemen whose profit margin depends on clients not knowing who they obtained their supply of APIs from so they cannot be cut out of the deal.

As a result, APIs are often shipped with documentation that does not indicate where they were made or by whom.

It is this practice that was largely to blame for the cough syrup poisonings in Panama.

In that case poisonous substances at some point in their international journey were mislabeled as a pharmaceutical grade syrup. The containers of this chemical passed through a number of middlemen enroute to Panama each of whom in a process called "neutralization" removed all information in the accompanying certificate of analysis regarding whom they obtained the supplies from.

The middlemen also did not conduct any of their own tests on the quality of the substance they were selling.

Given the current environment, importers, traders and end-users must take more responsibility for ensuring that the products, moving through international supply chains, are honestly labeled and safe for their ultimate use.

This will require improving traceability so ultimate consumers are able to track chemical compounds back to the original producer - the identity of whom should be clearly set out on the certificate of analysis accompanying these products.

Ideally, end-user manufacturers and consumers should demand this - not the lowest price.

In many instances, however, this approach will not be available to the poor in developing economies who form the ideal target market and dumping ground for substandard drugs in all their forms.

In developed countries drug-market problems involving poorly screened or misused APIs are most likely to turn up in the rapidly growing ultra price sensitive generic drug market.

Just a few months ago Able Laboratories, a now bankrupt and delisted New Jersey-based generic drugs manufacturer with strong connections to the Indian pharmaceutical sector saw its former vice president in charge of quality control and three supervising chemists plead guilty to, in the words of the US Department of Justice, "rampant falsification and manipulation of testing data on its drugs."

Interestingly, the vice president also pled guilty to securities fraud for insider trading activity conducted in relation to the former Nasdaq-listed company's shares.

This was no small operation. Company shares had risen from 17 US cents (HK\$1.33) in 1999 to a high of US\$26.50 in May of 2005.

This high was rapidly followed by the announcement of concerns over the company's quality assurance system which resulted in a 75 percent plunge wiping out US\$340 million of shareholder value in one day. Related actions by the FDA led to the largest drug recall in US history.

The outlook is not completely bleak. Current concerns over quality control regarding APIs and other inputs are having some impact and the regulatory structure is evolving if slowly.

US Pharmacopoeia, a nonprofit organization that works with drugmakers and regulators to set drug-quality standards, has recently opened offices and labs in both Shanghai, China, and Hyderabad, India.

USP is introducing programs and standards into these markets that the best and most ambitious of the local pharma industry are enthusiastically embracing.

They recognize that adoption and participation in international best practices ingredient verification programs will set them apart from the pack in the eyes of both foreign regulatory authorities and consumers.

This in turn will strengthen their own brands, better prepare them for global expansion and ideally squeeze out those problematic middlemen.