Have your say.
Email yourview@pharmatimes.com

inbox

Pharma's tsunami approaches

From *Hedley Rees, managing director, Biotech PharmaFlow*

Dear Editor,

PharmaTimes Magazine kindly printed my letter last year on manufacturing and supply issues in the industry. It aimed to draw attention to pharma's abysmal performance in making its own products. Since then it has all kicked off.

Pharma quality issues, shortages and adulterated materials entering the supply chain have now reached the person in the street. At the end of October, following several high-level congressional committee investigations into supply chain shortcomings and a raft of competent authority dictates on do's and don'ts in the supply chain, President Obama issued Executive Order 13588 – 'Reducing Prescription Drug Shortages'. Even a US charitable trust (PEW) has written a damning report on how in 2008 toxic material was substituted for the real thing in the manufacture of heparin, killing nine people and injuring many more. And recently, it has been reported that Novartis is dealing with hundreds of millions of dollars in costs because of manufacturing issues. In short, the whole world is asking: "what is going wrong in the pharma supply chain"?

Yet still manufacture and supply does not appear to be on the radar of top industry executives – and if the above is not enough to get it there, consider the following:

- Regulators across the world are collaborating like never before to detect and remediate gaps in the supply chain
- Regulatory hurdles are being tightened by an order of magnitude to drive greater control into the supply chain
- The FDA has made it clear, from its coining of the term TWOFERS, that it will be pursuing the responsible Marketing Authorisation Holder executives when it finds issues at a manufacturer of their products, including taking legal action against them
- Decades of tactical outsourcing and off-shoring has left those marketing drugs, who are ultimately deemed accountable by the regulators, with very little control of what is going on.

These issues are not a quick fix, having their roots in supply chain neglect during drug development. So set aside for a moment the patent cliff, or low R&D productivity, or market access, or value-based pricing. There is a tsunami approaching the industry that will soon find its way to shore.

ABPI response to the Leveson Inquiry

From *Amanda Callaghan , director of corporate affairs, ABPI*

Dear Editor,

The media has a responsibility to report fairly and appropriately on the issues of health and medicine. For many patients, the media is an important source of information about diseases, medicines and healthcare. Sadly there are instances where reporting has been less than satisfactory and there has been a detrimental impact on patients. The Science Media Centre recently put forward a submission to the Leveson Inquiry in which it highlighted a number of cases of misreporting and sensationalist reporting that caused serious damage to patient populations, such as the MMR vaccine scare.

In its privileged position, with a direct relationship with the public, the media should provide a balanced view so that the public and patients can gather information and draw their own conclusions. The media has a responsibility not to engage in poor reporting, sowing the seeds of doubt about medicines that leads to lower compliance levels than we already have.

The media can also play a positive role and support efforts to improve public health in key areas by accurately reporting, for example, the story of vaccination or the dangers of smoking.

Misreporting can put patient health at risk and have a negative impact on the UK healthcare environment. The ABPI supports the recommendations put forward by the Science Media Centre and welcomes the opportunity provided by the Leveson Inquiry to review the role and responsibility of the media in medicine and healthcare.