The Implant Files: A Global Communications Crisis

In November 2018, the International Consortium of Investigative Journalists published the results of the largest-ever investigation into medical device safety. The Implant Files investigation, from the same organization that released the infamous Panama Papers in 2016, involved more than 250 journalists across 36 countries coordinating to look into the behaviors of the medical device industry around the world.

The findings were grim, among them:

Globally, **as many as 83,000 people have died** in the last decade as a result of faulty medical devices and **as many as 1.7 million injuries** could have occurred

A rare type of **cancer** has been linked to a widely used model of breast implants

Some devices in question were approved in the UK after being tested on **as few as 30 people**

Yet, absent from the conversation was the medical device industry itself. While the investigation's findings were hitting headlines from Australia to New York, mum was the word—with no major manufacturers commenting, they became the elephant in the room.

With this as the backdrop, we called on GLOBALHealthPR partners from three key markets affected by the Implant Files to get their take:

France

Marie-Hélène Coste
Owner, MHC Consulting

The Implant Files issue has started to affect our market and media coverage. After the story broke on Sunday, in only one business day there were more than 300 stories in French media and a few patients scheduled for prolapse surgery refused to have mesh implanted. Later in the week, Cash Investigation, a popular, nationwide French investigative journalism TV program, aired an episode addressing the scandal that further fueled the fire.

In the coming months, the increased scrutiny could potentially accelerate changes in the CE mark procedure, which was expected to be effective early 2020, as well as push medical professional societies and health authorities to establish more transparency and trackability through the creation of registries. It could also encourage new rules for surgeons who are faced with complex cases and generate more pluri-disciplinary regulations in the operating room.

We've been managing the crisis with one of our clients for weeks now and it's far from over. While they haven't specifically been mentioned, we're diligently working with them behind the scenes to address the issue proactively at the right time with the right message.

India

Priti Mohile
Managing Director, MediaMedic Communications

Our market and media coverage were significantly affected by the Implant Files. All the major newspapers carried the news. In response, on Friday 30 November the Health Ministry issued a declaration approving compensation for those with faulty Johnson & Johnson hip implants up to 12.3 million rupees ($175,000 USD) per patient. Patient claims will be subject to an application process and committee review.

The recent news coverage will almost certainly accelerate discussions around quality issues for various implants in the coming weeks and months. Most importantly, patients will ask doctors more questions before any procedure. The feeling that 'faulty' implants were being pushed to emerging markets is already playing out, and manufacturers have an opportunity to reassure patients and practitioners that their devices are safe and proven.

Medical device companies must provide proactive updates to media about quality and their role as a solution in the Indian health context to build their credibility. Consequent to this crisis, questions on pricing will surface, too. There are still likely to be twists and turns as the controversy continues to play out.

United Kingdom

Sophie Thompson
Senior Account Manager, Aurora Healthcare Communications

In UK media, widespread coverage of the Implant Files focused on safety concerns with silicon breast implants, which are still being used in the UK despite French regulators advising against them. The news was picked up by the BBC, Evening Standard, Guardian, The Telegraph and many others.

We expect more companies' products to come under scrutiny in the coming weeks and months. An influx of worried patients requesting reassurance from healthcare professionals is inevitable and, with winter looming, this will put additional pressure on the NHS, which is already under strain.

It is key that companies carefully consider their response and are prepared to comment on this topic. In the short term they should reassure patients and provide advice on what to do if they have any concerns. In the long term, companies should also consider what additional safety data they can collect for all their products, regardless of whether this is required by current regulations.

New medical device regulation will be in effect in Europe by 2020 but, at a time of uncertainty due to Brexit, the future regulation of both pharmaceuticals and medical devices remains uncertain in the UK.

For additional insights or communications support from local experts like Marie-Hélène, Priti and Sophie, please contact **GHPRHQ@GLOBALHealthPR.com**