Evaluate Vantage

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Event – Duodenoscope panel could cut Olympus's sales

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February's outbreak of device-associated drug-resistant bacterial infections in the US did not prompt a product recall despite several patient deaths. Instead the FDA has responded – three months later – with an adcom, whose recommendations next week could have a profound effect on the company at the centre of the case: Olympus.

The FDA's gastroenterology and urology devices panel is to review the use of duodenoscopes, some of which have been found to transmit superbugs from one patient to another owing to being almost impossible to clean properly. This situation is compounded by the fact that one of Olympus's devices has been sold in the US since 2010, but without having first obtained market clearance.

The panel's recommendations will affect all three companies that sell duodenoscopes in the US, but with an 85% share of the US market Olympus has by far the most to lose. And it is Olympus's scopes that were responsible for the outbreak of carbapenem-resistant enterobacteriaceae that infected 11 patients at California hospitals and killed two.

Unapproved…

Duodenoscopes are used for visual examination of the duodenum during a procedure known as endoscopic retrograde cholangiopancreatography. Nearly 700,000 of these operations were performed last year in the US on patients with cancer, gallstones and other digestive issues.

The main device that has been linked to the outbreak is the catchily named TJF-Q180V, which Olympus started selling five years ago. It was first suggested that hospital staff had been remiss in their cleaning of the device before it was reused on the next patient, and in mid-February Olympus issued updated reprocessing instructions.

But the plot thickened when it emerged in March that the FDA had never granted the device any form of market approval or clearance. Olympus had been selling it in the US without permission – and the FDA had not noticed.

And the TJF-Q180V had such a dominant market position that the FDA felt it could not pull it from sale as doing so would mean too few duodenoscopes would be available to meet clinical demand.

Since 2013 the FDA has received around 75 reports of contaminated devices, but because one adverse event report can include several patients the actual number of infections could be higher. The coming adcom will seek to address the problem by evaluating whether duodenoscopes – including those sold by Fujifilm and Hoya in the US – are safe and effective.

…And unassailable?

Panellists will consider effectiveness of and guidelines for cleaning and sterilising duodenoscopes, as well as surveillance of the devices and the level of evidence required for labelling claims. They will also discuss appropriate patient selection for future procedures. If the recommendations are strict they could cut into Olympus's market.

The company does not publish exact US revenue figures for TJF-Q180V, but its Endoscopes division had global turnover of $2.8bn in 2014 – 40% of its overall sales.

Olympus's share price has been unaffected by the allegations, and is in fact up 2.3% over the past three months. Presumably this is because its position in the market is all but unassailable.

A 510(k) clearance application for TJF-Q180V has now been submitted. Ordinarily a device linked with infection and death would stand a poor chance of getting past the FDA. But when it is already in such demand that the agency believes that it would endanger patients to yank it – despite it never having been properly regulated – it would appear that the FDA has no choice but to wave it through.

As strategies go, bypassing the regulator and selling your device anyway is a risky one, but Olympus seems to have made a success of it. But next week's adcom might limit the circumstances and number of patients in which these devices can be used, and if it does Olympus has the most to lose.

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