Antibiotic Incentives Not Enough To Tackle Superbugs, Say GlobalData Analysts

A mixture of sequestration cuts is hindering the shift of American medicine from treatment to prevention of disease, and could leave US residents vulnerable to the growing threat of infectious diseases, according to analysts from leading research and consulting firm GlobalData.

From hospital superbugs carbapenem-resistant Enterobacteriaceae (CRE) and methicillin-resistant Staphylococcus aureus (MRSA), to new mutated strains of gonorrhoea, more pathogens are becoming drug-resistant. However, research into new antibiotics and the provision of vaccines is under threat due to budget cuts. For example, the Centers for Disease Control and Prevention (CDC) is expected to see its budget slashed by close to US$450m, or about 8% of its total funding for FY2013. According to CDC Director Dr. Tom Frieden, the cuts will compromise the agency’s fundamental ability to protect people from infectious disease outbreaks and epidemics.

Despite the escalating need for novel antibiotics, Big Pharma has been decreasing antibiotic R&D. The expensive, lengthy drug approval process, low prices, short duration of antibiotic therapy, and competition from generics has led pharmaceutical companies to shift their focus towards more profitable therapy markets, such as cancer and cholesterol therapeutics.

The Generating Antibiotic Incentives Now (GAIN) Act came into force in October 2012, providing incentives for pharmaceutical companies to develop novel antibiotics including fast track status and priority review with the promise of speeding up approval from the FDA. Antibiotics approved under the GAIN Act also have an additional five years of market exclusivity giving them an extra financial boost.

However, Dr. Brad Tebbets, GlobalData's Analyst covering Infectious Diseases, refers to the GAIN Act as a “stopgap solution”, stating: “These carrots will not be large enough to entice Big Pharma to revive its antibiotic R&D, though they could increase interest in smaller companies with novel antibiotic pipelines.” He cites a low return on investment as the main issue for antibiotic development, stating: “The GAIN Act acknowledges the need for novel antibiotics, but does little to address the underlying issues affecting drug discovery and antibiotic drug resistance. The incentives outlined in the GAIN Act do little to truly increase the profitability of antibiotics.

“The GAIN Act also does nothing to prevent the spread or emergence of drug-resistant organisms. Without the implementation of antibiotic stewardship and surveillance, any novel antibiotics developed as a result of the GAIN Act will only provide temporary relief before microbes develop resistance.”

Furthermore, the upcoming sequestration-related spending cuts in the US, resulting from the Budget Control Act of 2011, are set to reduce government spending by US$1 trillion, and dramatic cuts experienced by federally funded health agencies will also dictate the fate of preventable infectious diseases.

The Centers for Disease Control and Prevention (CDC) is expected to see its budget slashed by close to US$450m, or about 8% of its total funding for FY2013. The American Public Health Association (APHA) claims that these reductions are expected to prevent the vaccination of 30,000 children and 20,000 adults against largely preventable diseases such as tuberculosis, measles, tetanus, and whooping cough. The incidence of chronic infections such as viral hepatitis, HIV, and other sexually transmitted diseases (STDs), would also be expected to increase, as prevention programs lose funding. The CDC have estimated the annual cost of STD treatment in the US to be upwards of US$15.6 billion, placing an enormous economic burden on an already cash-strapped healthcare system, says Dr. Christopher Pace, GlobalData's Infectious Disease analyst.

Dr. Tebbets suggests that revamping FDA guidelines is another way to encourage antibiotic R&D. He explains: "Changing the FDA safety threshold for antibiotics to align closer to other life-threatening indications such as cancer would decrease review time and cost, increase the probability of FDA approval, and enable doctors and patients to assess risks when treating a deadly, drug-resistant infection. Without lasting reform like the aforementioned examples, the need for antibiotics will only escalate, and Big Pharma will continue to pursue more profitable therapeutic avenues."

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