Revealed: full scale of vaccine blunders

US authorities horrified by conditions at factory in BSE-tainted polio drug scare

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The drug factory at the centre of the polio vaccine scandal has a history of contamination and production blunders, leading to fears that its vaccines against other diseases are unsafe.

The lives of thousands of old people and children have been put at risk by drug shortages caused by a catalogue of problems that have plagued the Medeva vaccines plant on Merseyside. One serious incident led to British soldiers being sent abroad without protection against Yellow Fever.

Last year, investigators from the US Food and Drug Administration (FDA) were horrified by the conditions they found at the plant in Speke, near Liverpool, which also makes vaccines against flu, tuberculosis, tetanus and Hepatitis B.

On Friday, the Department of Health was forced to recall Medeva's oral polio vaccine after it was discovered that the firm had potentially been using BSE-infected material.

This weekend, an investigation by The Observer can reveal that the problems surrounding the polio vaccine may prove to be the tip of the iceberg.

A week-long inspection by the FDA last summer into the production of the flu vaccine Fluvirin at the plant found Medeva had failed to:

• 'clean, maintain and sanitise equipment at appropriate intervals to prevent malfunction or contamination';

• maintain systems to prevent unacceptable levels of toxins and bacteria contaminating the production process;

• ensure batches of vaccines 'conformed with all established standards, specifications and characteristics'; and

• prove that vaccines on doctors' shelves would be free from 'bacteria and fungi'.

Last October the FDA's director of compliance, Steven Masiello, fired off an official warning letter to Medeva's head of primary production, John O'Brian, telling him to sort out the problems or have its product banned from entering the US. Fluvirin is used by some 20 million Americans and more than a million British people, many of them elderly.

Although the extent of the excess levels of toxins and bacteria at the Speke factory is not known, in extreme cases, contaminated vaccines can lead to severe adverse reactions, including toxic shock and fever. In the old and fragile, the impact could be lethal.

The FDA letter, seen by The Observer , contains the disclosure that instead of dealing with the problems, managers at the plant wanted to raise the level of contamination deemed to be acceptable.

Sources familiar with the company's operations claim that there were serious production problems running through the factory and abuses were routinely ignored.

Although it is not known what other contamination problems the factory had, it is known that production difficulties were not confined solely to the manufacture of the flu vaccine.

The Observer has learned that the company was forced to stop making its Yellow Fever vaccine Arilvax, leading to a widespread shortage throughout the country. The Ministry of Defence last night confirmed that the situation became so serious that earlier this year it sent British soldiers on overseas missions without protection against Yellow Fever. Many travellers were also unable to get vaccinated against the horrifying tropical disease, which attacks the stomach and kidneys. The company has still not restarted production.

This March, The Observer revealed that production problems at the Medeva factory had led to warnings of a tuberculosis epidemic after the company failed to supply sufficient quantities of vaccine to health authorities. Three months after the FDA inspection the shortage of TB vaccines led to the suspension of routine school vaccinations.

Liberal Democrat consumer affairs spokesman Norman Baker is now calling for an immediate investigation into events at the Speke factory and a full explanation from the Department of Health.

He also said that the Medicines Control Agency (MCA), the body which regulates drug companies, had serious questions to answer about why it had failed to take any action.

Baker said: 'The Department of Health and the MCA have completely failed to act in the interests of public health.

'In their desperate attempts not to undermine the vaccination programme, they have tried to sweep all problems under the carpet. As a result, public confidence has been shattered.

'When will they learn that the answer is not to cover up, but to identify problems and deal with them immediately?'

The Medicines Control Agency refused to answer any questions posed by The Observer about Medeva's vaccines and production at the Merseyside factory.

A spokeswoman for the Department of Health said: 'The MCA would not have allowed vaccines to be produced at this factory unless it was sure it was safe.'

The troubled Speke plant has changed hands twice over the past year. When the problems were first identified by the FDA, it was owned by Medeva Pharma, which was bought by Celltech in January. Just last month, the vaccine business was sold on to Oxford-based Powderject and is now called Evans Vaccines.

A spokesman for Powderject said the company had first looked at buying the business last year, but pulled out after reading the FDA report. After receiving reassurances that the problems had been resolved it went ahead with the purchase: £56 million has been spent on improvements and the management team has been changed, although a number of senior personnel remain with the firm.

The FDA confirmed that it had not reinspected the plant since its October warning letter, but was satisfied that problems were now being dealt with. It has authorised the import of the flu vaccine this year.

A spokeswoman said: 'The FDA would not allow this vaccine to enter the country if it was not safe.'