

## Meningitis Vaccine under Scrutiny in UK

AGENCY FINDS MORE THAN 16,000 ADVERSE REACTIONS SINCE LAST YEAR

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Last November, the British government instituted a mass national immunization program designed to vaccinate all children under 18 against meningitis C, a rare but potentially fatal brain disease. A series of government documents obtained by *The Observer*, a British newspaper, has revealed that more than 16,000 adverse reactions possibly linked to two vaccines have been reported in the past 10 months, including 12 deaths that occurred in people after being vaccinated.

The vaccines in question, Meningitec and Meninjugate, are designed to offer protection from meningitis C, which strikes approximately 1,500 people in the United Kingdom every year. The disease causes an inflammation of the membranes that surround the brain and spinal cord; it can also lead to hearing loss, kidney failure, brain damage or limb amputation. The disease occurs most frequently in young children, with symptoms including high fever, severe headaches, nausea, rashes and neck stiffness. About 10% of those infected with meningitis C die from the disease.

Since the immunization program began in November 1999, it has been under review by the Medicines Control Agency (MCA) and the Committee on Safety of Medicines (CSM), which use a system called the Yellow Card Scheme to report possible adverse reactions to drugs and vaccines. Under the scheme, doctors, pharmacists, coroners and dentists are advised to submit suspected adverse reactions to pharmaceuticals or new vaccines to the MCA or CSM - even if they are not completely sure whether the vaccine caused the reaction. The MCA and CSM, in turn, investigate all causes of death and assess Yellow Card reports to determine any safety issues that may be associated with a new drug or vaccine.

According to the Committee on Safety of Medicines, more than 15 million doses of the vaccines have been distributed in the U.K. Statistical analyses conducted by the British Department of Health, claim the vaccine has reduced the number of meningitis cases by as much as 85 percent, particularly among children aged 15-17 and infants less than a year old.

Figures compiled by *The Observer*, however, appear to contradict those published by the government. According to their statistics, there has been only an 18 percent drop in the total number of meningitis cases, from 713 cases during the first eight months of 1999 to 587 through the same time frame this year. Moreover, in parts of London, East Anglia and the West Midlands, there has even been a rise this year in the number of people diagnosed with the disease.

*The Observer* also reported that as of August 29, MCA and CSM had received 7,742 Yellow Card reports associated with the meningitis C vaccine, with symptoms ranging from headaches and dizziness to vomiting and convulsions. Although each report corresponded to one patient, many reports listed more than one reaction (for instance, nausea and headache), bringing the total number of adverse reactions that may have been caused by the vaccine to 16,527 - approximately one reaction for every 907 doses given.

In addition to the adverse reactions, 12 deaths occurring in people who had been recently vaccinated have been reported to the CSM. Seven of the deaths were a result of sudden infant death syndrome (SIDS); one patient died of a convulsion 10 days after being vaccinated.

While those numbers are high, the actual numbers may be much higher. The Department of Health estimates that only 10-15 percent of reactions are reported using the Yellow Card Scheme. Based on that estimation, the actual number of people experiencing adverse reactions to the meningitis vaccine could be in the tens of thousands.

Health officials have downplayed those numbers, insisting that the vaccine has saved lives and prevented disabilities. A statement released by CSM and the Joint Committee on Vaccination and Immunisation in August said that "the balance of risk and benefit is overwhelmingly favourable" and that "there is no suggestion that this vaccine has led to any deaths."

As worried parents and lawmakers seek a peaceful conclusion, the situation has angered parents across the U.K. and has caused some people to call for a halt to the immunization program until more tests have been conducted.

"I am not convinced by government reassurances," said Isabella Thomas, a member of Justice Awareness Basic Support, a vaccination support group. "We are receiving daily calls from parents whose children have had serious reactions. We believe the government introduced it far too quickly."

Adam Finn, a pediatric expert at Sheffield Children's Hospital, added that the vaccine was safe, but that it had induced adverse reactions in a number of children. Finn also said that the government has a duty to give the public all relevant information about the vaccine. "The public has sufficient intelligence to make the decision for themselves," he said. "The way to get them to accept it is to tell the whole story."

#### Possible Conflict of Interest Among Committee Members

The situation regarding the safety of the meningitis program was further called into question in September, when it was learned that four of the medical experts responsible for advising the government on the meningitis vaccine's safety had financial ties to one or more of the vaccine's manufacturers.

Professor Janet Barbyshire, a member of the Committee on Safety of Medicines and director of the Medical Research Council, was found to have received support for academic research from Wyeth and Chiron, the makers of the Meningitec and Meninjugate vaccines currently used in the U.K.

In addition, three members of the government's Joint Committee on Vaccination and Immunisation were shown to have declared interests in vaccine manufacturers. One member, Dr. David Goldblatt of the Institute of Child Health, was found to have served on an advisory panel for Wyeth and to have received research grants from both Wyeth and North American Vaccines, which produces a third meningitis vaccine (Neisvac). Another, Professor Keith Cartwright, received funding to "evaluate candidate meningococcal vaccines" for use in the United Kingdom.

"This is a question of propriety," said Norman Baker, the Liberal Democrat party's consumer affairs spokesman, who has tabled parliamentary questions about the financial interests of the committee members. "There must be enough independent people around to give advice without turning to those who clearly have a conflict of interests. I am not questioning their academic credentials, but with the

best will in the world, their judgments must be looked at in that context."

*Dynamic Chiropractic* will continue monitoring the controversy regarding the meningitis C vaccine in the United Kingdom. Stay tuned for an update on the immunization program in a later issue.

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