Vaccine for Japanese B encephalitis in Australia

The Australian government has reversed a 1991 decision to ban the use of vaccines against Japanese B encephalitis (JE). The Australian Drug Evaluation committee (ADEC) will announce the decision within the next month.

According to an article in the *Medical Journal of Australia* (1994; **160:** 795–97), JE is endemic in most of Thailand and the Indian subcontinent, where it causes disease in the young and the elderly. It also causes intrauterine infection and fetal death if acquired during the first or second trimester of pregnancy. Cases of JE have occurred in expatriates in many parts of SE Asia, Okinawa, China, Manchuria, and far eastern Siberia, mostly in rural areas. In that *MJA* article Dr Brian Mulhall of Sydney University and Prof Henry Wilde and Prof Visith Sitprija, both of Chulalongkorn University in Bangkok, say that although the ratio of overt disease to exposure is low, clinical encephalitis is severe and has a 25% mortality. About 30% of survivors have a long-term neuropsychiatric disability.

Vaccines against JE have been available in Japan since 1954, and are recommended in the UK for people planning to stay in rural areas of Asia for more than a month. A JE vaccine was fully licensed in the United States in December 1992. A JE vaccine became available for individual Australian patients after approval from the federal Health Department in 1987. The government's main health advisory body, the National Health and Medical Research Council, made a preliminary recommendation that use of the vaccine could continue, but the Health Department suspended use in 1991 because of concerns over adverse reactions.

Mulhall et al argued that this concern was an overreaction to case-reports. They said that adverse events following JE vaccines are no more common than with any other vaccine. The article, published before news of ADEC's decision was made public, recommended the vaccine be made available for people planning long-term stays in JE-endemic regions or rural areas in Asia.

Mark Ragg

Transfusion and Japan's product liability law

The Product Liability Law was passed unanimously by the national Diet on June 22 and will come into effect from July 1, 1995. It contains an accessory resolution that virtually excludes liability on transfusion products: "Complications of blood transfusion such as those caused by contamination of viruses whose complete removal by existing technology is impossible cannot be considered as product defects".

The law will simplify the very stringent procedures that consumers must now follow to start lawsuits against manufacturers of defective goods. This law will cover all manufactured goods, including medical products. Like that in the European Union, the law holds manufacturers responsible for their products for 10 years after shipping or, in medical cases, 10 years after appearance of symptoms. Although the concept of a product liability law was first discussed in parliament nearly 20 years ago, critics have identified loopholes. The "presumption provision", according to which the product is assumed to be defective if the manufacturer is unable to prove it to be otherwise, has been dropped. Included in the law is the "development risk refutation right", which the manufacturer could use for its defence if it proved that the consequences had not been forseeable at the time of development.

The controversial point is the accessory resolution, which was included at the last moment after heated debate. The Transfusion Society of Japan strongly opposed application of the law to transfusion products, claiming that it would not be able to continue its present services if it had to constantly bear in mind the possibility of lawsuits on transfusion complications. Its stance was that blood products are parts of a body and not manufactured products. The government argued that these products contained components not produced in the body, such as anticoagulants and preservatives, and therefore could be considered manufactured products.

The Transfusion Society's worry is not unfounded. 198 cases of complications were reported to Japan Red Cross Blood Centers in 1993. A large proportion were due to allergic reactions but 15 were deaths due to graft-versus-host disease. Furthermore, although post-transfusion hepatitis B infection is now considered virtually completely preventable in Japan, 4 cases of hepatitis B virus infection, and 6 of hepatitis C virus infection, were reported; of these, 2 died of fulminant hepatitis.

Transfusion complications due to human error are not rare either. A Ministry of Health and Wealthfare (MHW) survey, conducted in March, 1994, of 1030 hospitals under the Japan Red Cross Blood Center, revealed that 14% had had transfusion-related accidents in the past 10 years. MHW's guidelines on transfusion procedures drawn up in 1989 include the setting up of blood transfusion treatment committees in hospitals to control transfusion operations. Only 19% of the hospitals in the survey had this system in place and only 23% had doctors with special responsibility for transfusions.

Even without covering transfusion products, the product liability law is a large step forward for those seeking compensation for medical accidents, many of which do not come to light. The very existence of the law is sure to accelerate change in Japan's authoritarian doctor-patient relationship. To what extent the exception for transfusion products will be exercised is not clear, nor is how the provision will be actually applied—much will depend on the courts. But already hospitals have increasingly begun to obtain patient consent before transfusion. In turn, this trend has encouraged less liberal use of transfusions and has promoted autotransfusion.

Makoto Yawata

Twist at Prof Allain's appeal

The Supreme Court of Appeal in Paris reached a decision last week on an appeal by Prof J-P Allain against his conviction arising from the haemophilia/HIV prosecutions relating to events between March and October 1985. Allain's appeal questioned the validity of applying the 1905 Act Against Adulterated Foodstuffs to the supply of blood products by a state transfusion service. An indication that something unusual was at stake was the appearance of the full bench of 25 judges. It first heard the defence case against the applicability of the Act, and then heard the prosecutor also argue that the first court of appeal was incompetent to give judgment since, he said, the prosecution should have been on wilful poisoning, which should have been heard in a criminal court instead of the Correction Court.

In view of the current mood in France, Allain's legal advisers recommended withdrawal of the plea. The Supreme Court of Appeal concluded that the initial hearing had been held under competent authority and therefore the sentence must stand but found against the application for a change to the alternative charge of wilful poisoning. They stated that new evidence was needed to show intention of poisoning .

Already several plaintiffs have taken charges of wilful poisoning against, amongst others, the Prime Minister, the Minister of Social Affairs, the Minister of Health at that time, and the leading civil servants in each of their cabinets and have indicated their intention to also include Allain and other doctors. These charges are being met with scepticism in France both on the grounds that people condemned under one court should not be examined again under a different heading by a second court. Another weakness in the haemophiliacs' case is that, as far as can be ascertained, some of the individuals involved contracted their infection