

INFORMATION FOR PATIENTS
Approved April 7, 2004

Aventis Pasteur has announced a voluntary recall of several lots of its Rabies Vaccine MIRV (Merieux Inactivated Rabies Vaccine) that had been distributed in several countries around the world. **The lots being recalled passed all safety tests required by international health authorities.**

MIRV contains only inactivated (killed) rabies virus. A routine quality assurance test has shown that a single batch of vaccine contained some weakened (non-killed) virus. Therefore, **this batch was never released and never left the manufacturing site.**

As a precautionary measure, Aventis Pasteur has decided to voluntarily recall all other batches that were manufactured during the same time period.

It is important to understand that:

- The batches that are now being recalled have passed all quality controls mandated by international agencies, including those to detect non-killed virus, and are fully effective.
- The virus used to manufacture this vaccine is a weakened virus, used especially for vaccine manufacturing and much less virulent than the virus found in the wild,
- Even if some non-killed virus were present in the vaccine that is now being recalled, which is highly unlikely, this weakened virus would be administered at the same time as the vaccine that protects against it,
- Rabies vaccine, when properly used, is effective in preventing disease due to wild rabies virus.
- A person vaccinated with recalled vaccine will develop immunity to rabies, just as though non-recalled vaccine had been used. We are recommending additional steps to ensure that a high level of immunity develops as rapidly as possible, which is always the desire when immunizing against rabies.

This means that, having received one or several doses of recalled vaccine, you will be protected against rabies as soon as the full course of vaccination is completed. The best way to do this varies based upon individual circumstances. That is why we recommend that you seek advice from the physician who gave you your rabies vaccinations. Detailed information is available to your physician from Aventis Pasteur and from international agencies such as the U.S. FDA, the British Medicines and Healthcare Products Regulatory Agency, and others, on the best measures to undertake.