

<p>Recall of Rabies Vaccine Aventis Pasteur MSD: Batches X0071-6 and X0712-1 Advice to clinicians</p>

The Alert

Following discussions with The Irish Medicines Board, Aventis Pasteur MSD sent an alert to relevant healthcare professionals over recent days informing them of a recall of the above two batches of Rabies Vaccine BP (Aventis Pasteur MSD). A recent quality-assurance test identified the presence of non-inactivated Pitman-Moore virus (an attenuated vaccine strain) in a single product lot, which **was not distributed**.

The Significance

The manufacturing process does not use a wild (i.e. naturally occurring) rabies virus, but rather an attenuated or weakened strain of virus called the Pitman-Moore vaccine strain. The attenuated vaccine strain has been tested in animal models and has been shown to be less infectious than wild rabies virus. The Pitman-Moore strain produces a protective immune response, which is why it is used to make the vaccine. Rabies Vaccine BP is developed and marketed as an inactivated vaccine, meaning that any virus in the vaccine has to be killed before it is given to humans. Finding non-inactivated (i.e., live) virus in a lot after it was manufactured indicated a failure in the manufacturing process, and the vaccine may not be safe to give to humans. The vaccine lot containing non-inactivated virus was not distributed.

The Recall

As an additional precautionary measure Aventis Pasteur MSD has initiated a voluntary recall of vaccine batches that were manufactured during the same period as the lot that contained non-inactivated Pitman-Moore virus. Batch numbers X0071-6 and X0712-1 were distributed in Ireland. Other batches were distributed to other countries where similar action is being taken. It is important to emphasise that batch number X0071-6 and X0712-1 have passed all of the quality assurance tests required in Europe and the USA and that includes a test to confirm that the virus has been inactivated. Aventis Pasteur MSD has contacted all its customers who have been supplied with the specified batches and all unused quantities of these vaccines have been quarantined and uplifted.

The People Affected

The batches recalled were first distributed in Ireland on 24th October 2003, so this alert only affects people who have received rabies vaccine from these particular batches since that date. Approximately 1,300 doses of these batches of vaccine have been administered by General Practitioners, Hospitals, Health Centres and Travel Clinics in Ireland.

The Action Required

It is necessary to contact recipients of the above referenced batches with a view to implementing appropriate treatment as described in the flow chart below. Although it is highly unlikely that persons who received a dose of rabies vaccine from either recalled batch were exposed to the non-inactivated Pitman-Moore vaccine strain of rabies virus, a theoretical possibility exists. This possibility is regarded as negligible to nil.

It is recommended that recipients of a recalled vaccine complete the additional vaccine course, insofar as is possible, either before travel or while abroad. A cell culture rabies vaccine should be given and is usually available at recognised travel clinics worldwide.

Where practicable, Aventis Pasteur MSD will assist in arranging additional vaccination where the recipient is currently abroad.

Human Rabies Immune Globulin (HRIG)

Human rabies immune globulin (HRIG) is not being used in the treatment of recipients of recalled batches in Ireland. HRIG is a human blood product, is not without risk and is in extremely short supply. For these reasons its use in Ireland is confined to high-risk rabies exposure situations.

The Facts

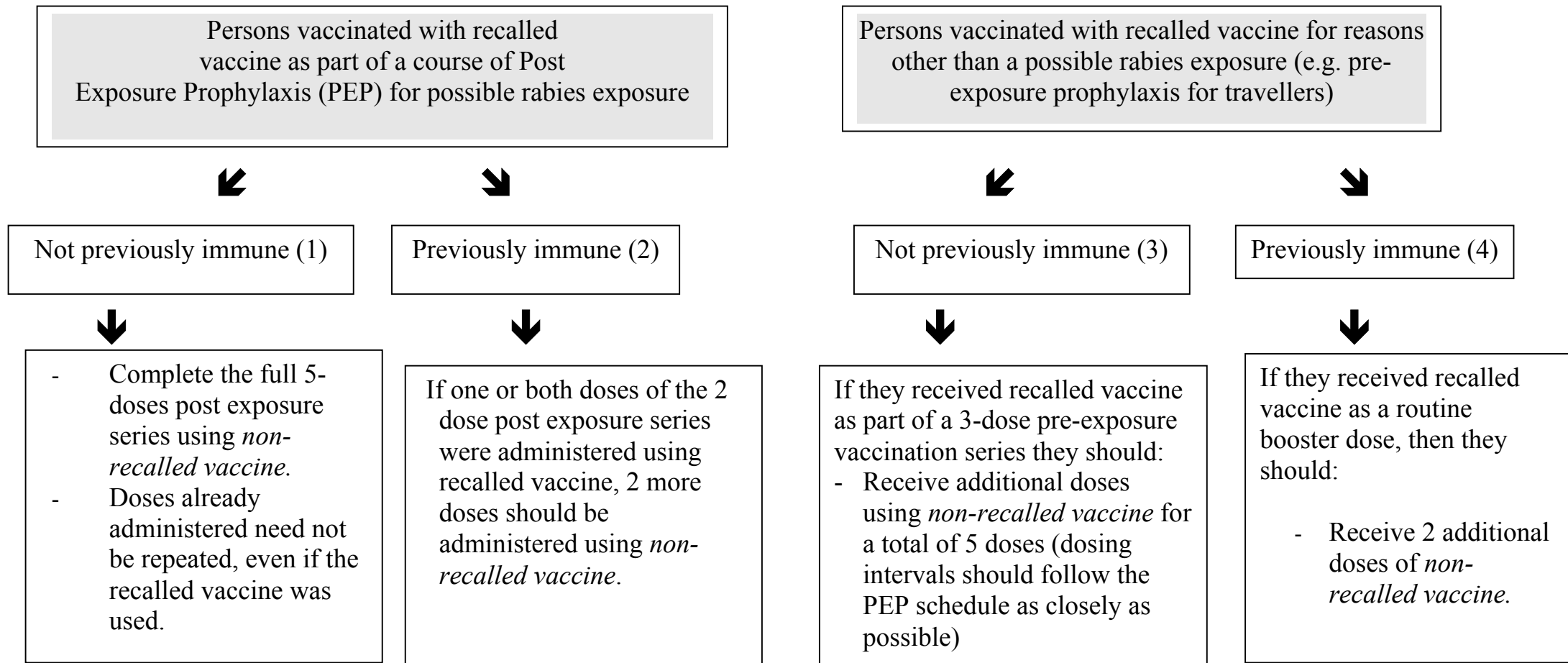
No unusual adverse events, and in particular, no case of vaccination-induced rabies are known to have occurred following administration of the recalled lots of Rabies vaccine BP. Recalled lots have been in use in Ireland since October 24th 2003 and in the USA since September 23rd 2003 without any unusual adverse events being reported. No human cases of rabies have ever been transmitted through currently licenced rabies vaccine products in Ireland or the UK.

Further Information:

A document entitled "Information for Healthcare Professionals and Patients", is available on IMB, and NDSC and websites.

7th April 2004

Recommendation for people who receive rabies vaccine (Aventis Pasteur MSD: Batch X0071-6 and 0712-1)



1. Persons who have not received at least 3 doses of vaccine at some point before the possible rabies exposure.
2. Persons who have received at least 3-doses of vaccine at some point before the possible rabies exposure (e.g. a full, pre or post-exposure vaccination series)
3. Persons who have not received at least 3-doses of vaccine at some previous time.
4. Persons who have received at least 3-doses of vaccine at some previous time (e.g. a full, pre or post-exposure vaccination series)