

Recall of Rabies Vaccine BP Batch X0071-6 (Aventis Pasteur MSD)

Q&A

Q: What lots have been recalled and why?

A: In the United Kingdom, the recall affects Rabies Vaccine BP Batch Number X0071-6 which was produced during the same time period as the non-distributed batch containing non-inactivated Pitman-Moore virus. The lots recalled internationally including X0071-6 passed all release tests, including testing to confirm the absence of live virus. They are being recalled only as a precautionary measure.

Q: When were these lots distributed in the United Kingdom?

Only batch number X0071-6 was distributed in the UK, first on 26th February 2004. So this alert only affects people who have received rabies vaccine from that particular batch since that date. Approximately 6,000 doses of this batch of vaccine have been distributed to General Practitioners, Hospitals, Health Centres and Travel Clinics in the UK.

Q: What is the significance of finding non-inactivated virus in the vaccine?

A: Rabies Vaccine BP is developed and marketed as an inactivated vaccine, meaning that any virus in the vaccine has been killed before it is given to humans. Finding non-inactivated (i.e., live) virus in a batch after it was manufactured indicates a failure in the manufacturing process, and the vaccine may not be safe to give to humans. It is important to note that no batches containing non-inactivated virus are known to have been distributed; the recall is a precautionary measure.

Q: What does “attenuated strain of rabies virus” mean?

A: The manufacturing process does not use a wild (i.e., naturally occurring) rabies virus, but rather an attenuated or weakened (also known as “fixed”) 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 pathogenic than wild rabies virus. However, the Pitman-Moore strain produces a protective immune response, which is why it is used to make the vaccine.

Q: Does the recall affect vaccine that was distributed in other countries?

A: The manufacturer has indicated that additional batches of recalled vaccine were distributed internationally. More than 20 countries are affected by the recall. Similar to the batch recalled in the UK, the internationally distributed batches passed all release tests, including testing to confirm the absence of live virus. The manufacturer is working with regulatory authorities to determine batch numbers of vaccine and countries that may have received recalled vaccine.

Q: What should providers and distributors do with any remaining vaccine doses from recalled lots?

A: General Practitioners, Hospitals, Health Centres and Travel Clinics in the UK who have any remaining doses of lot X0071-6 should not use them but should quarantine the remaining doses. Aventis Pasteur MSD is contacting all distributors and providers with additional detailed information on their disposal.

Q: I am a healthcare provider treating a patient who received recalled vaccine-what should I do?

A: Healthcare providers who are treating a patient who received a dose of rabies vaccine since February 26th 2004 should check the patient's record to verify whether they received a dose from batch number X0071-6. They should treat persons who have received recalled vaccine according to the recommendations outlined in:

http://www.hpa.org.uk/infections/topics_az/rabies/Rabies_Vaccine_Recall.pdf

Q: I received a dose of the recalled vaccine - could I develop rabies?

No unusual adverse events—and in particular, no cases of vaccination-induced rabies—are known to have occurred following administration of the recalled

batches of rabies vaccine. Recalled batches have been in use in the USA since September 23rd 2003 and in Ireland since October 24th 2003 without any unusual adverse events being reported. Nevertheless, although this is a highly attenuated strain of vaccine virus, it could theoretically cause rabies in humans. No human case of rabies has ever been transmitted through currently licensed rabies vaccine products in the UK.

It is extremely important that all patients currently receiving a rabies vaccination series (e.g. for travel overseas) complete their immunisation series on time, using non-recalled vaccine. Do not omit any injections that have not yet been administered, and do not delay their administration.

Q: I received a dose of rabies vaccine since February 26th 2004 but I am not sure if I received recalled vaccine - what should I do?

A: Anybody who has received rabies vaccine since February 26th should be contacted by the surgery/travel clinic that administered the rabies vaccine if they received a dose of the recalled batch of vaccine. If in doubt, patients should check with the surgery/travel clinic that administered the vaccine(s).

Anyone who received RABIPUR (the rabies vaccine manufactured by Chiron) is not affected. Anyone who received an Aventis Pasteur MSD rabies vaccine from a batch different to X0071-6 since February 26th is not affected.

Q: Who will pay for the costs of revaccination?

A: Aventis Pasteur MSD is working to source additional supplies of Rabies Vaccine BP and will contact customers as soon as these doses become available. Aventis Pasteur MSD will also re-imburse the costs of vaccinating patients affected by this recall if immediately available vaccine has already been used for this purpose. Aventis Pasteur MSD will be contacting customers with further information about this.

Q: Is the identification and treatment of persons who received recalled vaccine considered a medical emergency?

A: It is important to keep in mind that none of the recalled batches were known to contain non-inactivated virus and that the recall is being initiated as a precaution. While the situation is urgent and warrants a diligent approach by healthcare providers, it is not a medical emergency. Every effort should be made to contact the patient to inform them of the alert.

Q: How should persons who completed a 3-dose pre-exposure vaccination series in which recalled vaccine was given be treated?

A: Persons who have completed a full 3-dose pre-exposure series in which recalled vaccine was used should receive 2 additional doses of vaccine, regardless of how much time has elapsed since the last dose of vaccine. Dosing intervals should follow the post-exposure prophylaxis (PEP) schedule as closely as possible (i.e. Day 0,3,7,14, 30).

Q: Do persons who completed a 3-dose pre-exposure vaccination using recalled vaccine and who are now overseas need to return to the UK

A: If they have received rabies vaccine from batch number X0071-6 as part of a 3 dose pre-exposure prophylaxis then they require two additional doses using non-recalled vaccine while abroad or, failing this, on their return to the UK.

Aventis Pasteur MSD are advising travelers to contact the relevant British Embassy for referral to a reliable medical centre while abroad. Travelers should keep all receipts for reimbursement by Aventis Pasteur MSD. If travelers who were vaccinated with the recalled batch return without having been vaccinated while abroad, they should seek attention immediately to ensure that they complete the required number of doses as soon as possible.

Q: How should persons who have started but not yet completed a 3-dose pre-exposure vaccination series in which recalled vaccine was given be treated?

A: For persons who have not yet completed all 3 doses of the series (i.e., only received 1 or 2 doses), give additional doses to complete a total of 5 doses including the doses of recalled vaccine already given. Dosing intervals should follow the PEP schedule as closely as possible (i.e. Day 0,3,7,14, 30)

Q: How should persons who have completed a full 5 dose pre-exposure vaccination series in which recalled vaccine was given be treated?

A: Persons who have completed a full 5-dose post-exposure series in which recalled vaccine was used do not require any further doses of vaccine.

Q: How should persons who have started but not yet completed a 5-dose post-exposure vaccination series in which recalled vaccine was given be treated?

A: Persons should complete the full 5 doses post exposure series using non-recalled vaccine. Doses already administered need not be repeated, even if the recalled vaccine was used. Dosing intervals should follow the post-exposure prophylaxis (PEP) schedule as closely as possible (i.e. Day 0,3,7,14, 30)

Q: How should persons who have received recalled vaccine as a single booster dose be treated?

A: Persons who have received recalled vaccine as a booster dose should receive 2 additional doses of non-recalled vaccine, one immediately and one 3 days later.

Q: Are the medical recommendations for persons who have received recalled vaccine different for pregnant or breastfeeding women

A: Rabies vaccine is not contraindicated during pregnancy or while breastfeeding, and the recommendations for treatment of persons who received recalled vaccine do not differ for pregnant or lactating women. Even if a pregnant or lactating woman is exposed to rabies, her unborn or breastfeeding infant is not at risk unless the mother develops clinical signs of infection. Following the recommendations outlined by HPA will help to ensure negligible risk. These can be found at:

http://www.hpa.org.uk/infections/topics_az/rabies/Rabies_Vaccine_Recall.pdf

Q: How should persons who do not fit the current medical recommendations be treated?

A: The situations for which rabies vaccine may be administered vary widely, and it is possible that some persons may have received recalled vaccine under circumstances not addressed here. Persons seeking clarification for unusual circumstances may contact the duty doctor at the Health Protection Agency, Specialist and Reference Microbiology Division (Tel: 020 8200 4400) or HPA Communicable Disease Surveillance Centre (Tel. 0208 200 6868)