

## **RABIES VACCINE RECALL**

### **INFORMATION FOR HEALTHCARE PROFESSIONALS AND PATIENTS**

#### **1. What has happened?**

The Irish Medicines Board (IMB), the Department of Health and Children and the National Disease Surveillance Centre (NDSC) have been notified that Aventis Pasteur MSD Ireland, as a precautionary measure, is voluntarily recalling two batches of Rabies Vaccine BP that have been supplied in Ireland. Approximately 1300 doses of this batch of the vaccine have been distributed to General Practitioners, Hospitals, Health Centres and Travel Clinics in Ireland. It is estimated that approximately 500 people may have been administered with this vaccine.

#### **2. Why are they taking this action?**

During routine testing a batch of Rabies Vaccine was found to contain live attenuated (weakened) rabies virus, from the strain used to make the vaccine. The vaccine normally contains only inactivated (or killed) virus. **This batch was never distributed**, but the company is recalling all other batches that were made at the same time as a precautionary measure. Unused packs from recalled batches are no longer available to the public. In Ireland batches X0071-6 and X0712-1 of Rabies Vaccine BP manufactured by Aventis Pasteur MSD are affected by this recall. Other batches available in Ireland and Rabies Vaccines from another supplier are not affected by the recall.

#### **3. What is the risk from live attenuated rabies virus?**

The attenuated (weakened) strain of the virus is used to make the vaccine. It is much less virulent than the strain of rabies virus that would be caught from animals, and it produces a protective immune response, which is why it is used to make the vaccine. It is normally inactivated as part of the manufacturing process.

#### **4. Is there likely to be a risk to humans receiving affected batches?**

No. All of the batches that have been distributed have passed all of the quality tests required in Europe and the United States of America. This includes a test to confirm that the virus has been inactivated. This recall is being carried out as a precautionary measure because other batches, including X0071-6 and X0712-1, were made at the same time as the batch that was found to contain live attenuated virus. Only batches X0071-6 and X0712-1 have been distributed in Ireland; the other batches were distributed to other countries, where similar action is being taken.

#### **5. What should people do?**

The batches being recalled in Ireland were first distributed on the **24th October 2003**, so this will only affect people who have received Rabies Vaccine since that date.

Anyone who has been vaccinated since then will need to check which vaccine and which batch he or she received by contacting the doctor or healthcare professional who administered their vaccine. Anyone who received an Aventis Pasteur MSD Rabies Vaccine from a different batch since 24<sup>th</sup> October 2003 is not affected.

**6. What should patients do who have already received the batches that are being recalled in Ireland?**

The advice that is being given following consultation between the IMB, NDSC, DoHC, national and international experts is as follows:

- Anyone who is part way through, or has recently completed (since 24<sup>th</sup> October 2003), a course of pre-exposure prophylaxis (normally 3 doses) should receive additional doses of a different batch of Rabies Vaccine, to make a total of 5 doses. Anyone who received recalled vaccine as part of a booster dose should receive 2 additional doses of non-recalled vaccine.
- Anyone who is part way through a course of post-exposure prophylaxis (normally 5 doses for unimmunised individuals) should complete the full 5-dose series using non-recalled vaccine. Anyone who has recently completed (since 24<sup>th</sup> October 2003) the 5 dose series does not need to receive any additional doses. Previously immune persons who received 1 or 2 doses of the recalled vaccine as part of the post exposure series should be given 2 more doses of vaccine, using non-recalled vaccine.

Persons receiving postexposure prophylaxis should not omit or delay any remaining injections; the remaining injections should be administered using non-recalled vaccine. Recalled vaccine is considered fully immunogenic, and previously administered doses can be considered a dose in a postexposure prophylaxis regimen.

**7. What effect does this recall have on the availability of Rabies Vaccine BP in the Ireland?**

The IMB states that Ireland has sufficient stocks of alternative Rabies Vaccine to cater for the short to medium term and is also working with pharmaceutical companies to ensure future stocks.

Rabipur (a rabies vaccine manufactured by Chiron) is not affected by this recall and is an alternative Rabies vaccine.

**8. 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 lots of the Rabies vaccine. No human cases of rabies have ever been transmitted through currently licensed rabies vaccine products in Ireland. Although it is highly unlikely

that persons who received a dose of recalled vaccine were exposed to live attenuated vaccine strain rabies virus, all individuals who received vaccine either for post-exposure protection or pre-exposure protection are recommended to contact their doctor regarding additional rabies vaccine doses that are recommended to provide full protection.

All patients currently receiving a rabies vaccination series should complete the immunization series on time, using non-recalled vaccine. Do not omit any injections that have not yet been administered, and do not delay their administration.

**9. I am abroad, but my doctor contacted my family in Ireland to tell me that I received the recalled vaccine – what must I do?**

If you have received vaccine from a recalled batch as part of a course of pre-exposure prophylaxis, then you require two additional doses as recommended from a non-recalled batch either in Ireland or in a developed country where a vaccine is available. Aventis have indicated that they will provide assistance to people overseas who need further information.

**10. How about those travelling before completion of the additional course of vaccination?**

Recipients of recalled vaccine who are recommended additional vaccine doses are recommended to complete the vaccine course as far as possible either before travel or while abroad. Rabies vaccine is usually available at recognised travel clinics. Aventis have indicated that they will provide assistance to people overseas who need further information.

**11. Are the vaccines currently licensed in Ireland considered interchangeable?**

There are two types of rabies vaccine currently licensed in Ireland: Rabies vaccine BP (Aventis Pasteur) and Rabipur (Chiron) and they can be used interchangeably in treatment regimens.

**12. Are the medical recommendations for persons who have received recalled vaccine different for pregnant or breastfeeding women?**

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 for rabies unless the mother herself has developed clinical signs of infection.

**13. How is this being managed in other countries?**

Additional lots of vaccine produced during the same time period were distributed to other countries. All vaccine lots distributed passed all release tests, including testing to confirm the absence of live virus. Aventis is recalling batches from those countries. The follow-up of patients who received the recalled vaccine may differ in

various countries based on national guidelines for rabies vaccination. Recommendations may vary based on the judgment of authorities in those countries and such factors as the World Health Organization Expert Committee on Rabies Report, which takes into account variables such as availability of biologics and perceived risk.

#### **14. What is rabies?**

Rabies is a viral infection of the nervous system that can infect almost all mammals, including humans. Foxes, dogs, raccoons, bats and skunks can all act as reservoirs for rabies. Worldwide, the principal hosts for rabies are the domestic dog, and bats, particularly insect eating bats. Once infected, the virus becomes concentrated in an infected animal's saliva and is passed on through the animal's bite. It can also be passed on by contact of infected saliva through scratches, licks on broken skin and mucous membranes. It is one of the oldest recognised diseases in man.

#### **15. Who should be immunised against rabies?**

Various groups of people should be immunised against rabies. Groups for whom vaccination should be considered include: anyone who travels to remote places where medical treatment may not be available; people who handle bats; anyone whose work involves working with imported animals; health and laboratory workers who work with the virus.

##### ***Pre-exposure protection***

The vaccine when given in three doses before exposure provides protection (pre-exposure protection). Persons at on-going risk of exposure should be boosted every two or three years.

##### ***Post exposure protection***

Following a rabies exposure (e.g. bite of rabid dog) non-immunised persons are given rabies vaccine (5 doses over a month period) and rabies specific immunoglobulin.

If the person was already vaccinated against rabies before the exposure they are given booster doses of rabies vaccine (but no rabies immunoglobulin).

#### **16. Who will pay for the costs of revaccination?**

The manufacturer, Aventis Pasteur, has indicated that it will ensure that any additional doses of rabies vaccine considered necessary as a result of this vaccine recall are provided free of charge for persons requiring them. For more information, contact your doctor or health care professional who administered the vaccine or call Aventis Pasteur Medical Information at telephone 00 44 1628 785 291.

#### **Further information:**

This advice is available on IMB and NDSC websites: [www.imb.ie](http://www.imb.ie), [www.ndsc.ie](http://www.ndsc.ie).

If you have any further questions please contact Aventis Pasteur Information as follows:

For stock related issues call 01 4041688

For Medical Information enquiries contact 00 44 1628 785291