

From the Chief Medical Officer
Dr Henrietta Campbell CB



Department of
**Health, Social Services
and Public Safety**

An Roinn

**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

www.dhsspsni.gov.uk

URGENT COMMUNICATION

HSS(MD)11/2004

To:

- Medical Directors, HSS Trusts (*for onward dissemination to Infectious Disease Physicians and Travel Clinics*)
- Directors of Public Health, HSS Boards (*for onward dissemination to all general practitioners*)
- Consultants in Communicable Disease Control, HSS Boards
- Directors of Nursing, HSS Boards
- Dr Paul Rooney, Director of Public Health Laboratory

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Your Ref:
Our Ref: HSS(MD)11/2004
Date: 6th April 2004

Dear Colleague

RECALL OF RABIES VACCINE BY AVENTIS PASTEUR MSD LTD

The purpose of this urgent communication is to alert you to the fact that Aventis Pasteur MSD is recalling 1 batch of Rabies Vaccine BP in the UK as a precautionary measure. This is because a low level of contamination with live attenuated rabies virus was discovered in a single batch of rabies vaccine. The batch being recalled has passed European and US release procedures but was prepared at the same time as the faulty batch. The details of the affected batch are as follows:

Batch Number	Expiry Date	Pack Size	First Distributed
X0071-6	12/2005	Single dose vial + syringe of diluent	February 2004

A Drug Alert has been issued by the Medicines and Healthcare Products Regulatory Agency and is attached. A separate communication is being issued to pharmacy colleagues by the Chief Pharmaceutical Officer at DHSSPS.

Action

It would appear from our records that some vaccine doses from this affected batch have been distributed in Northern Ireland. Recipients of this letter are requested to quarantine all stocks of the affected batch of this product and return them to the supplier. Additional information is also provided in the attached Question & Answer Sheet.

Further guidance is being developed nationally by the Health Protection Agency and will be available on their website at www.hpa.org.uk.

Yours sincerely

Dr Lorraine Doherty
Senior Medical Officer (Communicable Diseases)

cc: Dr Brian Smyth, Regional Epidemiologist
Dr Jill Mairs, Regional Procurement Pharmacist
Dr H Campbell, Chief Medical Officer
Dr N Morrow, Chief Pharmaceutical Officer
Miss J Hill, Chief Nursing Officer
Dr E Mitchell, DHSSPS
Mr G Dorrian, DHSSPS



Medicines and Healthcare Products Regulatory Agency
Defective Medicines Report Centre
Market Towers
1 Nine Elms Lane
London
SW8 5NQ

Safeguarding public health Telephone: 0207 084 2574 Facsimile: 0207 084 2676

DRUG ALERT

CLASS 1 MEDICINES RECALL

Action Now - including out of hours

Date: 05 April 2004

EL (04)A/01

Our Ref: MDR 02-04/04

Dear Healthcare Professional,

Aventis Pasteur MSD

Rabies Vaccine BP (Rab/Vac)

PL 06745/0053

Batch Number	Expiry Date	Pack Size	First Distributed
X0071-6	12/2005	Single dose vial + syringe of diluent	February 2004

Aventis Pasteur MSD are recalling the above batch with immediate effect as a precautionary measure. This follows detection in a single batch, **which was not distributed**, of a low level of contamination with live attenuated rabies virus. The batch being recalled has passed European and US release procedures but was prepared at the same time as the faulty batch.

Recipients are requested to quarantine all stocks of the affected batch of this product and return them to their supplier for credit. Additional information is provided in the attached Q & A sheet.

Further information is available by calling Aventis Pasteur Medical Information Service on Freephone 0800 7311654, which is available from the 6th April 2004. Prior to this, further information is available by calling Vaccine Information Service on 01628 773737.

Primary Care Trusts are asked to bring this information to the attention of Community Pharmacists, General Practitioners and Specialists in communicable diseases/infectious diseases and Public Health by copy of this letter.

Yours faithfully

Graham Matthews

MHRA Distribution:

Regional Contacts for NHS Trusts and Provider Units

Chief Pharmacists: England, Scotland, Wales, Northern Ireland

Prison Health Policy Unit (DH)

Medical Supplies Agency (MOD)

Chief Pharmacists: Jersey, Guernsey, Alderney, Sark, Isle of Man, Gibraltar

Special Hospitals

National Care Standards Commission for distribution to Independent Health Care Establishments

Primary Care Trusts (England)

RABIES VACCINE RECALL

INFORMATION FOR HEALTHCARE PROFESSIONALS AND PATIENTS

1. What has happened?

Aventis Pasteur MSD is voluntarily recalling a batch of Rabies Vaccine BP that has been supplied in the UK. Approximately 6000 doses of this batch of the vaccine have been distributed to General Practitioners, Hospitals, Health Centres and Travel Clinics in the UK.

2. Why are they taking this action?

During routine testing a batch of Rabies Vaccine was found to contain live attenuated 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. In the UK only batch x0071-6 of Rabies Vaccine BP manufactured by Aventis Pasteur MSD is affected by this recall. Other batches available in the UK and Rabies Vaccines from other suppliers are not affected by the recall.

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

The attenuated 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, but its effect in man is not known. 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, were made at the same time as the batch that was found to contain live attenuated virus. Only batch X0071-6 has been distributed in the UK; the other batches were distributed to other countries, where similar action is being taken.

5. What should people do?

The batch being recalled in the UK was first distributed on 26th February 2004, 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. Anyone who received Rabipur[®] (the Rabies Vaccine manufactured by Chiron) is not affected. Anyone who received an Aventis Pasteur MSD Rabies Vaccine from a different batch since 26th February is not affected.

6. What should patients do who have already received the batch that is being recalled in the UK?

- Anyone who is part way through, or has recently completed (since 26th February 2004), a course of pre-exposure prophylaxis (normally 3 doses) should receive 2 additional doses of a different batch of Rabies Vaccine, to make a total of 5 doses.

- Anyone who is part way through, or has recently completed (since 26th February 2004), a course of post-exposure prophylaxis (normally 5 doses for unimmunised individuals, or 2 doses for previously immunised individuals) does not need to receive any additional doses but should complete the course.
- Any previously immunised individual, who received the affected batch as a booster, should not need to receive additional doses because the vaccine is still effective.

Use of Human Rabies Immunoglobulin (HRIG) should be considered for any previously unimmunised individuals who have received the first or second doses of their course, from the batch being recalled, within the past seven days, and who have not already received HRIG.

Further information on immunisation against Rabies can be found in:

Immunisation Against Infectious Disease 1996 - "The Green Book"

<http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/GreenBook/fs/en>

or in the current edition of the British National Formulary

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

Following the recall, Aventis Pasteur MSD do not currently have stock of Rabies Vaccine BP available. It is estimated that stock Rabies Vaccine BP will become available in the UK again from September 2004.

Rabipur[®] (the rabies vaccine manufactured by Chiron) is not affected by this recall.

8. Further information:

More detailed advice for clinicians is being prepared by the Health Protection Agency and will be published on their website.

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

Freephone 0800 7311654 from the 6th April.

Prior to this, further information is available by calling Vaccine Information Service on 01628 773737.