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DEPARTMENT OF HEALTH
AN ROINN SLAINTE
Shaping a Healthier Future

Minister Martin issues statement about Polio Vaccine distributed in 1998/9

The Department of Health and Children has been informed that one UK blood donor, the plasma of whose donation was used in Britain to make a batch of the product Human Serum Albumin, has recently been diagnosed as having the variant form of Creutzfeldt Jacob Disease (vCJD)

This person's donation was one of 22,353 used to make a pool. This in turn was combined with another pool to give a final dilution of 1/63,866.

This Human Serum Albumin was used by Evans/Medeva in the manufacture of Oral Polio Vaccine, as an essential stabilising agent. Approximately 83,500 doses of the polio vaccine in question were distributed in Ireland between 15 January 1998 and 30 January 1999. More detailed checking is taking place with the Health Boards in relation to the precise usage of this vaccine.

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It is not possible to state in medicine that there is absolutely zero risk, but expert advice, both national and international, available to the Department of Health and Children indicates that in this situation it is almost certainly the case.

Albumin has a long tradition of safety. This is based partly on the fact that the purification methods used in its manufacture eliminate the potential for infectivity. Albumin is produced at the last stage of a series of purification procedures. Recent studies of the various plasma fractions have shown no infectivity associated with albumin.

Polio vaccine is administered to children as part of the Primary Childhood Immunisation Programme at the ages of 2, 4 and 6 months, and a booster immunisation is given at primary school entry age. Some adults may also have received the vaccine as part of the recommended immunisations for travel to certain countries.

There is no longer any UK-sourced plasma material contained in any vaccine in use in Ireland.

Parents may contact their family doctor if they wish to enquire whether or not their child received vaccine from any of the batches concerned, as part of their primary immunisations.

Also, each Health Board has been requested to establish a telephone line which concerned parents can call to enquire whether or not their child received any of the vaccine, as a booster immunisation. This service will also enable reassurance to be given to parents.

The Health Board telephone numbers, which will all be fully operational from tomorrow, Wednesday morning, are:

East Coast Area Health Board }
Northern Area Health Board } 1800 454500 (4.00 p.m.- 12.00 p.m. midnight today and from 9.00 a.m. to 9.00 p.m. Wednesday to Friday)
South-Western Area Health Board }

Midland Health Board	1800 463646
Mid-Western Health Board	1800 202255
North-Eastern Health Board	1800 342424
North-Western Health Board	1800 200710
Southern Health Board	1800 742000
South-Eastern Health Board	1800 300654
Western Health Board	1800 201220

Additional information on this issue will be displayed on the Department's website (***www.doh.ie***) and on the websites of the Irish Medicines Board (***www.imb.ie***) and on the websites of the individual health boards.

Vaccine Batch Details (for information)

The numbers of the batches of Evans Polio Vaccine, with the product description POLIOV/10/1EI, are as follows:

Batch	Expiry date
E7213/01A	10/05/98
E7213/02A	10/05/98
E7213/02B	09/06/98
E8214/01A	02/08/98
E8214/01B	15/09/98
E8215/01A	24/12/98
E8215/01B	31/01/99

ENDS

19 December, 2000

Check against delivery

Speaking Note by the Minister for Health and Children, Micheál Martin, T.D. regarding Polio Vaccine in 1998/9

Ladies and Gentlemen

Thank you for coming here at such short notice in the week leading up to Christmas.

There are a number of experts present here with me and I will be introducing them individually and giving their backgrounds in a couple of minutes.

The reason we are all here is that the Department of Health and Children has been informed that one UK blood donor, the plasma of whose donation was used in Britain to make a batch of the product Human Serum Albumin, has recently been diagnosed as having the variant form of Creutzfeldt Jacob Disease (vCJD).

This Human Serum Albumin was used by Evans/Medeva in the manufacture of Oral Polio Vaccine as an essential stabilising agent. Approximately 83,500 doses of the polio vaccine in question were distributed in Ireland between January 1998 and January 1999. More detailed checking is taking place with the Health Boards in relation to the precise usage of this vaccine.

Check against delivery

Polio vaccine is administered to children as part of the Primary Childhood immunisation Programme at the ages of 2, 4 and 6 months, and a booster immunisation is given at primary school entry age. Some adults may also have received the vaccine as part of the recommended immunisations for travel to certain countries.

There is no longer any UK-sourced plasma material contained in any vaccine in use in Ireland.

What will concern parents and all of us is the potential risk and in advance of this announcement we have consulted the best national and international experts. Many of those experts are present here and you can raise with them the relevant issues.

In trying to assess risk I would say that while it is not possible in medicine to state that there is zero risk, in this situation it is almost certainly the case, because of the dilution factor in the manufacturing process, the purification methods used and the outcome of studies on infectivity with Albumin.

I want to stress that we will give you every bit of information which supports that risk assessment.

Check against delivery

Why am I making it public at this time? Because I believe I have no honourable alternative. The public right to know must outweigh any issues of timing. Yes - we could postpone it until after Christmas, but the danger of a sensational leak, without the opportunity to give the public accurate information on the issue, would be enormous. Of course, we are sorry to be disturbing families at this special time.

Since we received this information and confirmed it with British authorities last week, we have used the intervening time to supply background information, expert risk assessment and other data to G.P.'s, the primary source of administering the vaccine, Public Health Nurses, Health Centres, Hospitals and others so that they can respond to queries from parents and others concerned.

Health Boards will supply information through their web-sites and on telephone help-desks.

Now I want to introduce you to the experts who have advised us on this issue and they are available to answer any questions you may have.

Thank you all again for coming here today.

19 December, 2000