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HSS(MD)7/2001

To: All General Practitioners (for onward distribution
to practice staff including practice nurses)
All Community Pharmacists
Directors of Public Health
Consultants in Communicable Disease Control of HSS Boards
Directors of Nursing of HSS Boards
Directors of Pharmaceutical Services of HSS Boards and CSA
Medical Directors of HSS Trusts
Nursing Directors of HSS Trusts – for distribution to Health Visitors and
Treatment Room Nurses
Directors of Pharmaceutical Services of HSS Trusts
Regional Epidemiologist, CDSC(NI)

14 February 2001

Dear Colleague

Current vaccine and immunisation issues

This letter is to update you on several important immunisation issues, namely:

1. The latest concerns about MMR vaccine – page 1;
2. The Meningitis C immunisation programme – page 3;
3. Meningococcal immunisation for asplenic patients – page 3;
4. Meningococcal immunisation for pilgrims travelling to Saudi Arabia – page 4;
5. Influenza immunisation – page 4;
6. Acellular pertussis vaccine – page 6;
7. Annex 1 MMR questions and answers – page 8; and
8. Annex 2 Meningococcal immunisation for pilgrims travelling to Saudi Arabia – page 15.

1. MMR vaccine

- 1.1 Publicity given to an article by Drs Andrew Wakefield and Scott Montgomery has renewed media interest in MMR and concerns of some parents about the vaccine. Dr Wakefield has been in the forefront of suggesting a link between MMR vaccine and long term health problems, especially inflammatory bowel disease (IBD) and autism. Media interest has also focussed on the use of single antigen vaccines as opposed to the recommended combined vaccine. Annex 1 to this letter contains responses to some of the questions most frequently asked by parents.

- 1.2 Wakefield and Montgomery's article appeared in *Adverse Drug Reactions and Toxicological Reviews* on 21 January¹. The Government's independent expert committees, the Committee on Safety of Medicines (CSM) and the Joint Committee on Vaccination and Immunisation (JCVI), have both reviewed the paper. They have advised that the paper contains no new data relevant to the safety of MMR vaccine, that its analyses are incorrect and that it has failed to mention other published work that does not support their argument.

Statement by independent expert advisory committees

- 1.3 In the light of Dr Wakefield's article, the CSM conducted a further detailed review of the information available at the times of MMR licensing in 1972 and 1988 and the subsequent safety data of MMR vaccine. The Chairman, Professor Alasdair Breckenridge has said: "MMR vaccine is very safe. There is no question mark whatever over its licensing". Professor Michael Langman, Chairman of the JCVI has said: "My committee has independently considered all the issues and reached the same position as CSM. If there is a question mark, it is over the advice to have single vaccines."²
- 1.4 The BMA, RCGP, RCPCH, RCN and CPHVA have issued the following joint statement: "We welcome this positive statement from the Chairs of these expert committees about MMR vaccine. MMR is a safe and effective vaccine. By contrast, there is a real concern about having the vaccines separately, since children would be left unnecessarily at risk from these potentially serious diseases. We strongly recommend that children are protected with MMR".³
- 1.5 The suggested link between MMR and IBD and autism has been thoroughly considered now over a number of years by the CSM and the JCVI. The view of these committees remains that, on the scientific evidence available, there is no causal link between MMR vaccine, autism and bowel disease. This view is supported by the Medical Research Council and World Health Organisation (WHO). The WHO said on 24 January 2001: "WHO strongly supports the use of MMR vaccine on the grounds of its convincing record of safety and efficacy. The combination vaccine is recommended rather than monovalent presentation [single vaccines] when available and the disease burden justifies its use".
- 1.6 The overwhelming evidence from worldwide experience is that MMR remains the safest way to protect children against these three potentially serious diseases. The safety of combined MMR is supported by a great body of evidence while there does not appear to be such evidence on safety and efficacy when the individual vaccines are given separately. Giving children separate vaccines unnecessarily exposes them to the risk of life-threatening infection.
- 1.7 A new study by Kaye et al has been published on the BMJ website. The authors studied the records of 305 children with a diagnosis of autism between 1988 and 1999 in the UK General Practice Research Database. The study shows a notable rise in the diagnosis of autism from 1988 to 1999. Over this period there was no change in the proportion of children who had been immunised with MMR. The authors conclude that "These data provide evidence against a causal association between MMR vaccination and the risk of autism".⁴

- 1.8 It has been suggested that the administration of licensed single rubella vaccine to children will allow a practitioner to justify the importation of unlicensed measles and mumps vaccines. 'Immunisation against infectious disease' advises that rubella vaccine should be used for the protection of sero-negative women, and should not be used for immunisation of infants.⁵

Update of materials for professionals and the public

- 1.9 The present scare stories clearly worry parents. In order to try and encourage parents to have their children protected with MMR and to ensure that factually accurate scientific information is available to help them in their decision making, the Department will be working with the Health Promotion Agency to update at the information resources for both the public and health professionals. Updated leaflets and Factsheets are being prepared and will be published as soon as possible. In the meantime, Annex 1 to this letter contains responses to some of the questions most frequently asked by parents.

2. The Meningococcal C (Men C) immunisation programme

- 2.1 We would like to take this opportunity to thank and congratulate all involved in delivering the Men C programme. Implementing this important initiative involved much hard work and commitment from many people in the health and education sectors. The programme has been a wonderful achievement for the HPSS.
- 2.2 The impact of the Men C vaccination programme can already be seen – there was only one case of Group C meningococcal infection in the under 18 years age group in the six months from July to December 2000 compared with 17 cases in the same six month period in 1999.
- 2.3 It is important that parents remain alert to the signs and symptoms of meningococcal disease. The Men C vaccine does not protect against meningococcal B disease (now responsible for almost all childhood cases) and not all individuals have been immunised with the new vaccine.

Item of Service fee

- 2.4 We would encourage all practices to review their patient lists to ensure, in collaboration with the local Consultant in Communicable Disease Control (CCDC), any children or young people missed during the school campaigns are offered the Men C vaccine. An Item of Service Fee is now available for GPs giving the vaccine to anyone under 18 years of age. It is particularly important that vaccine is offered to anyone who was missed last year.

3. Meningococcal C (Men C) immunisation for asplenic patients

Meningococcal C (Men C) vaccine is now recommended for people with an absent or dysfunctional spleen

- 3.1 Patients with an absent or dysfunctional spleen (through operative splenectomy, functional hyposplenism or congenital aplasia) are at increased risk of overwhelming bacterial infection. Infection is most commonly pneumococcal, but other organisms such as Haemophilus influenzae type b (Hib) and meningococci may be implicated. Immunisation with pneumococcal, Hib and influenza vaccines is currently recommended for hyposplenic individuals.⁶
- 3.2 In view of the better efficacy and longer duration of immunity likely to be conferred by the MenC vaccine, the JCVI now recommends that it is offered to all patients with an absent or dysfunctional spleen. Up to now, meningococcal A&C vaccine was recommended only in high risk situations, such as travel to a high risk area.
- 3.3 When travelling to a high risk area for meningococcal infection, such patients will still require the additional protection conferred by polysaccharide A&C or quadrivalent (A,C,W,Y) vaccine.

4. Immunisation for pilgrims travelling to Saudi Arabia for Hajj or Umrah

- 4.1 Saudi Arabia requires pilgrims entering the country for Hajj or Umrah to be immunised against meningococcal A infection. Previously the UK has recommended meningococcal polysaccharide A&C vaccine.
- 4.2 Following an outbreak of meningococcal W135 infection associated with the Hajj last year⁷, the JCVI now recommends that the quadrivalent meningococcal polysaccharide vaccine, which provides protection against A, C, W135 and Y strains, is more appropriate.
- 4.3 One licensed product, 'ACWY Vax' (SmithKline Beecham), is available. Details are contained in Annex 2. The vaccine is indicated for adults and children aged two years and over. The vaccine should not be used in infants of less than two months. When issuing a certificate of meningococcal vaccination, doctors should indicate which vaccine has been given.
- 4.4 Children and young people travelling for Hajj or Umrah who have received Men C vaccine will still need the additional protection against A and W135 strains afforded by the quadrivalent vaccine. An interval of at least two weeks is recommended before administering the quadrivalent (or A&C) vaccine where MenC immunisation has only recently been given.
- 4.5 The Department has worked with the Multicultural Resource Centre to make this information available to the Muslim community in Northern Ireland.

5. Influenza immunisation

- 5.1 Congratulations are also due to all those involved in the influenza immunisation programme for 2000/01. Preliminary data for Northern Ireland to the end of December show a 67% uptake of vaccine in those aged 65 and over.

- 5.2 However, it is already time to start planning for next winter. The World Health Organisation has yet to make an announcement about the vaccine strains to be included in the 2001/02 vaccine, but manufacturers are already making their production plans and taking orders for vaccine for the 2001/02 season.
- 5.3 Full details of the immunisation programme for next year will be issued shortly. In the meantime, practices must assess their vaccine needs. This requires lists or registers to be made to include all patients aged 65 and over, those in residential care, and those under 65 in the 'high risk' groups, namely:

1. **Those with chronic respiratory disease, including asthma**

This includes chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema, bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis, asthma requiring continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission.

2. **Those with chronic heart disease**

This includes chronic ischaemic heart disease, congenital heart disease and hypertensive heart disease requiring regular medication and follow-up (but excluding uncomplicated controlled hypertension), and chronic heart failure.

3. **Chronic renal disease**

Including nephrotic syndrome, chronic renal failure, and renal transplantation.

4. **Diabetes**

Diabetes mellitus requiring insulin or oral hypoglycaemic drugs.

5. **Immunosuppression**

Due to disease or treatment, including systemic steroids equivalent to 20mg prednisolone daily for more than 2 weeks. However, please note that some immunocompromised patients may have a suboptimal immunological response to vaccine.

Hospitalisation for any of the above conditions within the last year would tend to be an indication for flu vaccine.

Use of medication as a marker

- 5.4 Some categories of medication near conformity to the risk criteria and could be accepted as surrogate markers of risk groups. These include, according to British National Formulary category:

1.9.4	Pancreatin
2.1.1	Cardiac glycosides
2.3.2	Drugs for arrhythmias
2.6.1	Nitrates
2.8	Anticoagulants
2.10	Anti-platelets, including aspirin
3.1.2	Antimuscarinic bronchodilators
3.2 & 6.3	Corticosteroids
3.3.2	Leukotriene receptor antagonists
3.6	Oxygen
6.1	Drugs used in diabetes
8.1	Cytotoxic drugs
8.2.2	Corticosteroids and other immunosuppressives
9.1.3	Drugs used in hypoplastic, haemolytic & renal anaemias
10.1.3	Drugs which suppress the rheumatic disease process
10.1.4	Some categories of medication near conformity to the risk criteria. However, they are not concordant with the risk groups and it is recommended they are only used as an ancillary aid in compiling disease-based registers.

6. **Acellular pertussis vaccine**

- 6.1 Stocks of monovalent acellular pertussis vaccine (APV) are no longer available and it is unlikely that it will become available in future. Stocks are exhausted in Northern Ireland. Acellular pertussis is available either in the DTPa vaccine (Infanrix) or as combined Hib and DTPa as (Infanrix Hib).

Yours sincerely

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- 1) Wakefield A and Montgomery S. Through a glass, darkly. *Adverse Drug React Toxicol Rev* 2000; 19(4): 265-283.
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- 3) BMA Press Release 'Joint professional statement on MMR' 12 January 2001
- 4) Kaye JA, del Mar Melero-Montes M, and Jick H. Mumps, measles, and rubella vaccine and the incidence of autism recorded by general practitioners: a time trend analysis. *BMJ* website 9 February 2001.
- 5) UK Health Departments. 'Immunisation against Infectious Disease' London: HMSO, 1996
- 6) Working Party of the British Committee for Standards in Haematology Clinical Haematology Task Force. Guidelines for the prevention and treatment of infection in patients with an absent or dysfunctional spleen. *BMJ* 1996; 312: 430-4.
- 7) CDSC. Meningococcal infection in pilgrims returning from the Hajj. *CDR Weekly* 2000; 10: 125, 149 and 169.

1. General statement on safety of MMR vaccine

MMR vaccine has an excellent profile and remains the best way to protect children against these three infections, measles, mumps and rubella, all of which can lead to serious health problems. The suggestion of an association between measles infection, measles vaccine, or MMR vaccine and inflammatory bowel disease (IBD/Crohn's disease) and autism was made by researchers at the Royal Free Hospital, London, led by Dr Andrew Wakefield. This claim has been rigorously examined by a number of independent expert advisory groups – the Joint Committee on Vaccination and Immunisation (JCVI) and the Committee on Safety of Medicine (CSM) – and their view remains that, on the scientific evidence available, there is no causal link between MMR vaccine and long term health problems such as bowel disease or autism. This view is supported by non-government organisations such as the Medical Research Council (MRC) and World Health Organisation (WHO) which “strongly endorses the use of MMR vaccine on the grounds of its convincing record of safety and efficacy.”

2. Does MMR cause autism and inflammatory bowel disease?

No. Reviews by both the CSM and the MRC did not identify a causal link between MMR and Measles/Rubella vaccines, autism and IBD. Such views are further reinforced by the report of a CSM Working Party and by a study undertaken in North Thames region, both of which found no evidence of a causal link between MMR and autism, by the latest report from the MRC's group of leading experts and also by recently published research from Finland. All results from vaccine trials published reaffirm the good safety profile and efficacy of MMR vaccine. A new study by Kaye et al has been published on the BMJ website. The authors studied the records of 305 children with a diagnosis of autism between 1988 and 1999 in the UK General Practice Research Database. The study shows a notable rise in the diagnosis of autism from 1988 to 1999. Over this period there was no change in the proportion of children who had been immunised with MMR. The authors conclude that “These data provide evidence against a causal association between MMR vaccination and the risk of autism”.

3. What about the recent article by Dr Wakefield in the Journal of Adverse Drug Reactions?

Independent expert committees and the WHO have reviewed this paper by Dr Wakefield and have advised that the paper contains no new data relevant to the safety of MMR vaccine, that its analyses are incorrect and it has failed to mention published work that proves their ideas wrong. Other scientists have not been able to reproduce the results claimed by Dr Wakefield regarding measles virus in the gut. His published observations regarding the onset of autism following MMR do not meet the scientific criteria required to suggest the vaccine is the cause. Other studies, which are not cited by Dr Wakefield in his review, do not find a link with autism or bowel disease.

4. Was the vaccine properly tested?

The MCA rejects any suggestion that combined measles, mumps and rubella (MMR) vaccines were licensed prematurely. The MCA is confident that the licensing process was properly conducted on the basis of the safety, quality and efficacy of the vaccines in adequate numbers of children.

Most of the studies enrolled children in the second year of life, although some enrolled children up to 13 years old. Details of adverse reactions were mostly recorded over 4-6 weeks post-injection because children returned for assessment of their responses to the vaccines around this time. In clinical trials less than 200 children were followed for one year. However, post-marketing reporting of adverse reactions provides much additional information on the safety of these products.

In 1972 the first measles, mumps and rubella combination vaccine was licensed in the UK (*MMR-I*). Information on protection in nearly 900 previously non-immune children and safety information on about 2,000 children was available.

MMR-II replaced *MMR-I* in 1987. Detailed safety data were available for more than 800 children who received *MMR-II* in clinical trials.

The approval of *Priorix* in 1997 was based on trials in which almost 6,000 children received the vaccine.

The approval of *Immravax* in 1989 (licensed but not in use in the UK) was based on clinical studies in which at least 6,400 subjects received the vaccine.

The approval of *Pluserix* in 1988 (not now licensed) was based on data from 672 children.

When the national immunisation programme started in 1988, there has already been substantial use in Scandinavia and the USA. A publication from Scandinavia in 1988 lists a total of 30 published studies where combined measles, mumps and rubella vaccines were studied. Of these, 17 were on the strains used in one particular vaccine (*MMR II*). Several hundred million doses had been given worldwide by 2000.

5. Has the safety of MMR been looked at in other countries?

Research conducted in Scandinavian countries has looked at measles infection and MMR vaccination in relation to reports of autism and Crohn's disease. In common with the latest information from the UK, no causal link was found between measles infection and MMR vaccination and either autism or Crohn's. For example, a study conducted in Gothenburg, Sweden over a ten year period during which time MMR vaccine was introduced into the childhood immunisation programme, showed that the incidence of autism was unaffected by the introduction of MMR. A recently published study from Finland of nearly 2 million individuals immunised with MMR carried out over a 14 year period did not receive any reports of bowel disease or autism associated with the vaccine.

6. What did the study in North Thames Region look at? What were the conclusions of the study?

The study in the North Thames Region was conducted by Professor Brent Taylor and researchers from the Royal Free Hospital (not the Royal Free Inflammatory Bowel Disease Study Group) in conjunction with the PHLS; it was published in the *Lancet* in June 1999. This study looked at the occurrence of autism in the North Thames region over a 15-year period that spanned the introduction of MMR. The researchers investigated the history of all 498 known autistic children born in North Thames since 1979 covering the period before and after the introduction of MMR vaccination in the United Kingdom (UK) in 1988. The study found:

- no increase in autism associated with the introduction of MMR in 1988;
- no difference in age of diagnosis between MMR immunised and unimmunised children;
- no difference in the MMR immunisation rates between those children with autism and the general population;
- and no link between the timing of MMR and the onset of autism.

The study, concluded: “Our results do not support the hypothesis that MMR vaccination is causally related to autism, either in its initiation or to the onset of regression”.

7. Do some children develop autism after vaccination?

MMR vaccine is first given between the ages of 13 and 15 months. Autism is usually diagnosed in the second year of life. This means that purely by chance, some children would have developed their autism around the time of vaccination. It certainly does not mean that MMR causes autism. Expert reviews do not show a cause and effect between MMR and autism.

8. Why are the numbers of children affected by autism in the UK on the increase?

It is true that there has been a steady increase in the numbers of children diagnosed with autism since the mid-80s. This observation is likely to be due to raised awareness regarding this condition, particularly amongst health professionals and parents. It is important to note that this increase in autism reports started before the MMR vaccination campaign in 1988. Research, including that from the North Thames study and the UK General Practice Research Database study, shows that there is no convincing evidence to suggest a causal link between MMR vaccination and autism.

9. What are the views of the autism voluntary body?

The National Autistic Society's view is that there is no evidence of an increase in the incidence of autism but that there is increased recognition of the range of the condition. Paul Cann, chief executive of the Society, has said "We do not believe that there is conclusive evidence of a link and we would never advise a parent not to have an MMR jab to reduce the risk of autism."

10. Should MMR vaccine be given as 3 separate vaccines?

There is no scientific evidence to support the safety of giving MMR as three separate vaccines. The UK has never recommended three separate injections. We are not aware of any country that recommends single vaccines rather than MMR. The policy is not based on financial considerations nor does it aim to deny parental choice. Separating vaccines puts children at risk and there is no evidence of a benefit over MMR. It is vital for children to be immunised with MMR or these three diseases will return.

11. What are the risks in using single vaccines?

- There is no evidence of harm from using MMR vaccine and there is no evidence of any added benefit from using single vaccines instead.
- There is much more evidence for the safety of MMR vaccine than there is for the single vaccines. WHO stated on 24 January 2001: “WHO strongly supports the use of MMR vaccine on the grounds of its convincing record of safety and efficacy. The combination vaccine is recommended rather than monovalent presentation [single vaccines] when available and the disease burden justifies its use”.

- Separating the vaccines – Dr Wakefield has suggested, without any scientific evidence, that there should be a gap of at least 12 months between vaccines. Children would remain at risk from the diseases they were not vaccinated against first. With MMR they would be protected against all the diseases at once.
- If 10% of children delayed their measles immunisation for two years we would have accumulated 225,000 susceptible children in the UK.
- Separating the vaccines exposes children to the risks of repeated reactions at the site of injection.

12. Why are single vaccines not available?

The MCA has restricted the importation of single dose vaccines on the grounds that under law, unlicensed medicines should not be imported when a safe and effective licensed alternative – that is, MMR - is available which meets patients' clinical needs. The MCA was also concerned about the evidence that the single dose mumps vaccine (Rubini strain) being imported was ineffective, that the mumps Urabe strain was less safe and, overall that the single dose vaccines would be worse for children than the combined MMR.

13. Can you get single measles, mumps and rubella vaccines privately?

The importation of unlicensed vaccine when a licensed alternative is available is restricted under the Medicines Act and this restriction applies equally to HPSS and private sectors.

14. In light of potential measles outbreak, why isn't the single component measles jab being made available?

It is not only epidemics of measles we are concerned about, it is also outbreaks of mumps and rubella. Over the last year there has been a large outbreak of mumps in Northern Ireland with about 1000 notified cases which started in mid-Ulster and has spread to Derry. The only way to prevent these diseases is through immunisation with MMR.

15. Are there circumstances in which single vaccines can be imported?

The MCA will not object to importation of an unlicensed single vaccine if a doctor decides, on his/her personal responsibility, that an individual patient of his/hers has "special [clinical] needs" which the MMR cannot meet.

16. When can unlicensed single vaccines be lawfully imported?

Legislation allows a licensed importer to import an unlicensed single vaccine and supply it in response to a doctor's prescription, issued on his/her personal responsibility, to meet the special needs of an individual patient.

17. What are "special needs"?

That is a matter for the responsible doctor. However, examples of a patient with "special needs" would include one who is sensitive to avian protein, or one who had already begun a course of treatment with mono-component vaccines.

18. Who can be supplied?

Doctors registered in the UK and for use in a registered pharmacy, a hospital or a health centre under the supervision of a pharmacist.

19. What restrictions are placed on the importer?

He/she must give written notification to the MCA in advance of each occasion he intends to import unlicensed medicines, normally no later than 28 days prior to importation, (but in cases of urgency the period of notice may be shorter by agreement.)

The MCA may object to import on grounds of safety or quality or if it is satisfied that the patient does not have a special need for the unlicensed product, for example, because there is a suitable *licensed* equivalent available.

Only small quantities – no more than 25 single doses or an amount sufficient for 25 courses of treatment not exceeding 3 months can be imported under each notification.

He/she must not advertise the vaccine even by issuing a catalogue, price list or circular.

20. What about record-keeping and public health protection?

The importer must keep records for a period of 5 years showing:

- i. the source of the product;
- ii. the person to whom and the date on which the product was sold or supplied;
- iii. the quantity of each sale or supply;
- iv. the batch number of the product;
- v. details of any adverse reactions to the product sold or supplied of which he/she is aware; and he/she must inform the licensing authority immediately of adverse safety or quality issues of which he/she has been notified.

21. What powers does the licensing authority have to prevent manufacture of a licensed single vaccine by a licensed manufacturer or the marketing of it by the product licence holder?

Having satisfied itself that it should issue the licences, the licensing authority may only intervene to protect public health if the licence holders fail to comply with their licence conditions, or the vaccine is not in accordance with its licence. Licences may be revoked, suspended or varied in those circumstances.

22. Why are parents in the UK are not given the choice of separate vaccines like in other countries?

No country in the world recommends MMR be given as 3 separate vaccines. In 93 countries around the world, MMR vaccine is used. Single rubella vaccine is available in the UK as it is recommended for women who are not immune. Some European countries still make use of this vaccine in addition to MMR. For example, the routine recommendation in France is MMR. France recommends that children are given single measles vaccine from 9 months of age **IF** they are in a nursery and there is a risk of a measles outbreak. These children then receive 2 further MMR vaccinations, at the same time as children in the UK. France does not recommend single mumps vaccine. Japan immunises against measles and rubella separately because they do not have a suitable MMR vaccine. However, Japan has suffered from endemic and epidemic measles. Between 1992-97, there were 79 measles deaths in Japan, and none in UK.

23. MMR vaccine contains 3 viruses in one: is this too much for young children?

Young children's immune systems cope daily, without difficulty, with many different challenges from the viruses and bacteria that are found virtually anywhere. In addition, the three components in MMR work at different speeds, so they don't all impact on the child at once. Splitting MMR into separate doses may be harmful because it exposes children unnecessarily to potentially serious diseases.

24. How serious are these diseases?

The success of MMR immunisation has resulted in notifications of measles being at their lowest ever levels. However, measles, mumps and rubella remain potentially serious diseases. In addition to those listed below, serious complications include:

Measles: pneumonia/bronchitis (1 in 25); diarrhoea (1 in 6); hospital admission (1 in 100); late onset Sub-acute Sclerosing Panencephalitis (1 in 8,000 children under 2). Since the beginning of 2000 over 1220 cases of measles have been notified in Dublin and there have been two deaths from measles. Additionally, in a recent outbreak in the Netherlands amongst unimmunised children 3 have died.

Mumps: swollen testicles (1 in 5 older males); meningitis/encephalitis (1 in 200-5,000); pancreatitis (1 in 30); deafness (usually with partial or complete recovery) (1 in 25). Mumps in pregnancy can lead to spontaneous abortion.

Rubella: encephalitis (1 in 6,000); bleeding disorder (1 in 3,000). Rubella during pregnancy can lead to spontaneous abortion or Congenital Rubella Syndrome (a child being born both deaf and blind).

25. What are the risks associated with the vaccine?

The recognised serious complications of the natural infections MMR protects against, compared with serious events following the vaccine, include:

	<i>rate after natural disease</i>	<i>rate after first dose of MMR</i>
<i>convulsions</i>	<i>1 in 200</i>	<i>1 in 1,000</i>
<i>meningitis/encephalitis conditions affecting</i>	<i>1 in 200 to 1 in 5,000</i>	<i>1 in 1,000,000</i>
<i>blood clotting</i>	<i>1 in 3,000</i>	<i>1 in 24,000</i>
<i>severe allergic response (anaphylaxis)</i>	<i>---</i>	<i>1 in 100,000</i>
<i>death</i>	<i>1 in 8,000 to 1 in 10,000 (depending on age)</i>	<i>NIL</i>

26. Consequences of fall in MMR vaccine uptake

MMR vaccine uptake at age two which had fallen over the past few years has now stabilised at around 92% in Northern Ireland. This is too low to maintain sufficient levels of protection in the population, especially against measles (95% is needed). Every child who is not immunised is at risk and also increases the risk of a return of these potentially very serious diseases. The latest scientific evidence shows MMR remains the safest way to protect children against these diseases.

Further information can be found on the following web sites:

www.immunisation.org.uk

www.doh.gov.uk

www.open.gov.uk/mca

Meningococcal immunisation for pilgrims travelling to Saudi Arabia

1. Last year, an outbreak of meningococcal W135 infection was associated with the Hajj. The JCVI therefore now recommends that the quadrivalent meningococcal polysaccharide vaccine, which provides protection against A, C, W135 and Y strains, is more appropriate.
2. One licensed product, 'ACWY Vax' (SmithKline Beecham), is available and the details are as shown below:
3. 'ACWY Vax' comes in a vial containing one dose of 0.5ml freeze-dried vaccine with an ampoule of diluent for reconstitution. It is indicated for both adults and children aged two years and over. Children 2 months to 2 years at risk may be immunised in some circumstances; immune responses may be achieved to serogroup A, W135 and Y antigens in these children, but are likely to be short-lived. The vaccine should not be used in infants of less than two months.
4. 'ACWY Vax' will be supplied in the following pack sizes:-

SB Code	Product	Pack size	Trade Price (excl VAT)	Order in multiples of	IMS Code	PIP Code	EAN Number
7309	ACWY Vax	1	£17.14	1	SCVM	275-8167	5000483730901

Ordering - With immediate effect, all orders for 'ACWY Vax' should be directed to your usual wholesaler/supplier:

5. For further information please contact:

Customer Response Centre
SmithKline Beecham Pharmaceuticals
Mundells
Welwyn Garden City
AL7 1EY

Freephone orders: 0808 100 9997
Freephone Enquiries: 0808 100 2228

6. The vaccine is indicated for adults and children aged two years and over. Immune responses may be achieved to serogroup A, W135 and Y antigens in children of less than two years, but are likely to be short-lived. The vaccine should not be used in infants of less than two months.