

Annex 2

SCOP 2001/ 4th MEETING
CSM 2001/16th MEETING

NOT FOR PUBLICATION

COMMITTEE ON SAFETY OF MEDICINES

SUB-COMMITTEE ON PHARMACOVIGILANCE

file

Title of paper: Possible neurodevelopmental effects of thiomersal in childhood vaccines	
Type of paper: For advice	
Product: Vaccines containing thiomersal	Assessor: Dr Rafe Suvarna
Active Constituent (s):	Previous Assessments: N/A
Therapeutic classification: Vaccines containing thiomersal	
Legal status: POM	

Contents	Page
Summary	2
Introduction	3
Data considered	4
Discussion	18
Conclusions and questions for the Committee	22
References	23
Index of attachments	25

Table 1: UK early childhood immunisations

Timing (Age)	Vaccines	Thiomersal (µg)	EtHg (µg)	Cumulative EtHG (µg)
2 months*	DTwP/Hib [†]	50µg	25µg	25µg
3 months*	DTwP/Hib [†]	50µg	25µg	50µg
4 months*	DTwP/Hib [†]	50µg	25µg	75µg

[†]DTwP/Hib = Diphtheria/Tetanus/Pertussis whole cell/Haemophilus Influenzae type B
 *Other vaccines (not containing thiomersal) given at these ages: Polio and meningitis C

It is current UK Department of Health's (DoH) policy to employ whole-cell Pertussis vaccines in the primary vaccination programme for infants, as it is believed that this offers greater protection than some acellular vaccines² (see annex 11).

2.2.2 Exposure to thiomersal from the WHO and US recommended schedules

The early childhood vaccination regimen recommended by the WHO involves exposure of 187.5µg EtHg in the first 14 weeks of life (table 2). Until recently, the same level of exposure has been recommended within the first 6 months of life in the US schedule. However, more recently the FDA has approved thiomersal-free Hepatitis B and DTP vaccines, which has resulted in a reduction in the potential exposure³. The recommended US vaccination schedule for 2001 is held at annex 1.

Table 2: WHO recommended vaccination schedule

Age	Vaccines	Hepatitis B (HB) Vaccine		EtHg dose (µg)	
		Scheme A	Scheme B	Scheme A	Scheme B
Birth*	BCG, OPV	HB1		12.5	
6 weeks	DTP1, OPV1, Hib 1	HB 2	HB1	62.5	62.5
10 Weeks	DTP 2, OPV2, Hib 2		HB2	50	62.5
14 weeks	DTP 3, OPV3, Hib 3	HB3	HB3	62.5	62.5
TOTAL				187.5	187.5

BCG = bacillus Calmette-Guerin, OPV= oral poliomyelitis vaccine, Hib = Haemophilus influenzae B
 DTP = diphtheria/tetanus/pertussis. * In 1999, prior to the general availability of thiomersal-free Hepatitis B vaccines, the policy the US policy to immunise all infants with Hepatitis B vaccine at birth was revised so that infants born to Hepatitis B surface antigen (HBsAg) negative mothers should be deferred by 2-6 months.

Assessor's comments: Until recently the US childhood vaccination schedule in the first 6 months of life has involved greater exposure to EtHg than occurs in the UK. Recently, the US has reduced exposure by employing thiomersal-free Hepatitis B and DTaP (acellular Pertussis) vaccines (see discussion).

2.3 Vaccine Safety Datalink study: Record-linkage study on neurological and renal effects of thiomersal in childhood vaccines

Only preliminary/draft unpublished data are available from this study.