

**Minutes of the**  
**Adverse Drug Reactions**  
**Advisory Committee**

**302<sup>nd</sup> Meeting**

**10 August 2007**



s22

10	VACCINES.....	47
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s22

10.2	VACCINE REPORTS.....	53
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s22

10.2.5	s22 Hib-Hep B s22 vaccines.....	58
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## **10 Vaccines**

### **10.1 Vaccine issues and published articles**

#### **10.1.1 Published papers**

The following were noted:

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- MS OY *et al.* Hepatitis B vaccine and risk of autoimmune thyroid disease: a Vaccine Safety Datalink study. *Pharmacoepidemiology and Drug Safety* 2007; 16: 736–745

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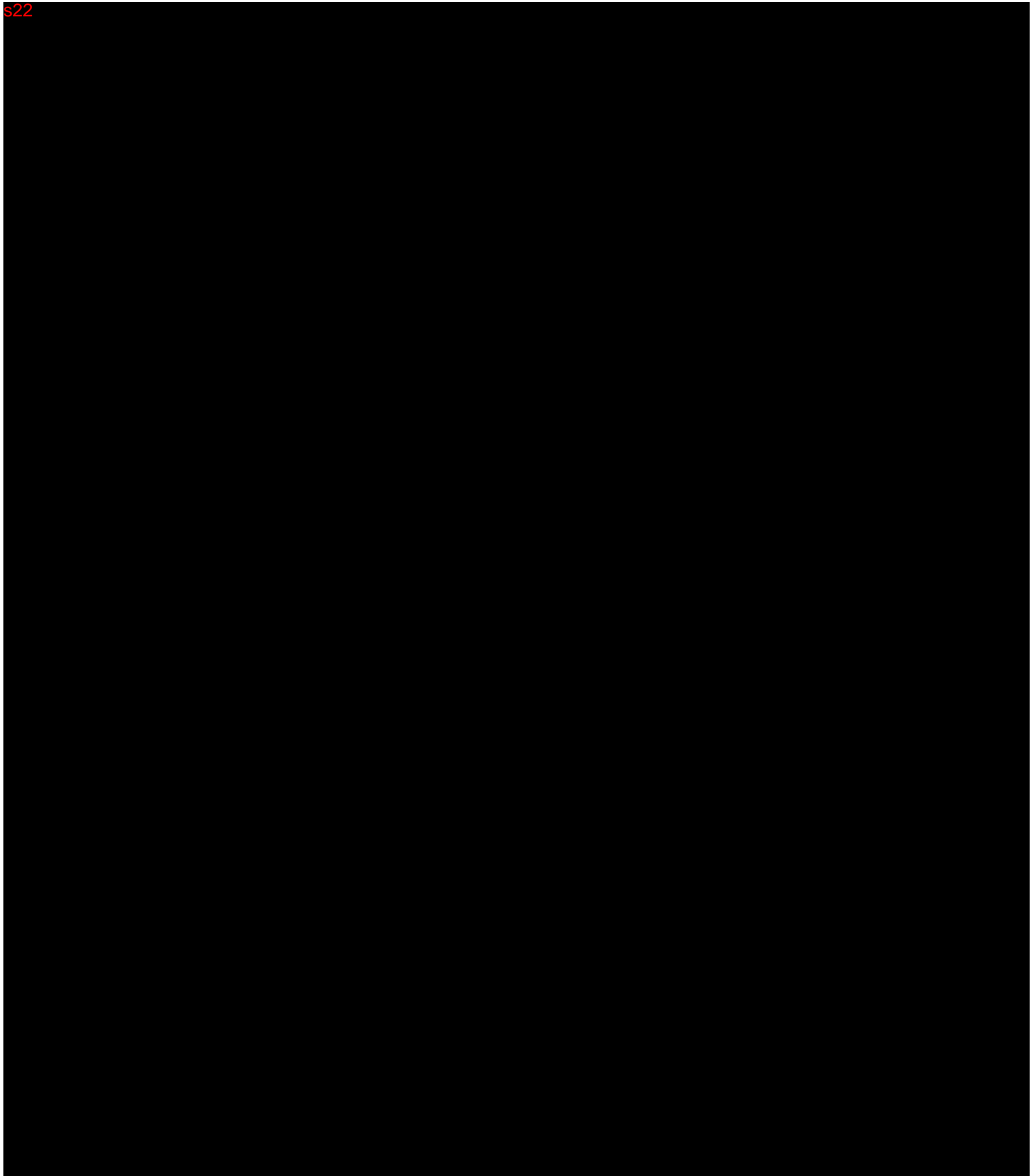




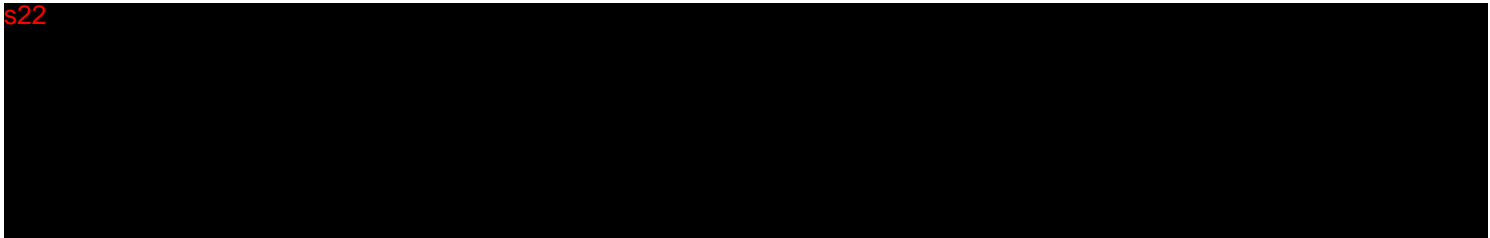








**10.2 Vaccine reports**



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The number of reports associated with each vaccine is shown in the table below.

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Vaccine	No. reports	Inject. site reaction	Convulsion seizure	Fever/pyrexia	Dyspnoea/apnoea	HHE	Other notable reports/important reactions / comments
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DTPa-IPV-HiB-Hep B	6	1	s22	2	1	s22	The reports of convulsion and of HHE both involved concomitant pneumococcal vaccine
Hepatitis B	8	1		1			CFS (s22 3 reports of dizziness but with s22 (s22 s22 s22 anaphylactic symptoms (s22 with s22 )
Hep A-Hep B	3	1					Facial palsy (s22
HiB-Hepatitis B	11			1	3	s22 s22	Both reports of HHE also involved s22 and s22 vaccines

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### 10.2.3 Hypotonic-hyporesponsive episode and [REDACTED], Hib-Hep B and [REDACTED]

Report [REDACTED]

A 2 month old male child experienced pallor, was hypotonic and difficult to wake, recurrently over [REDACTED], Comvax (Hib-Hep B) and pneumococcal vaccines. He recovered fully.

Report [REDACTED]

[REDACTED] hours after vaccination with [REDACTED] Comvax and [REDACTED] vaccines a 2 month old female began screaming, became very pale, floppy and was unresponsive. [REDACTED] and she recovered fully.

10.2.5 s22 and , Hib-Hep B and s22 vaccines

Report

A 4.5 year old male developed red spots behind his ears and bruises and was found to be thrombocytopenic s22 vaccination with s22 Comvax and s22 vaccines. There is a rare but known risk of thrombocytopenia with s22 vaccines, but all 3 vaccines were listed as being suspected.

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