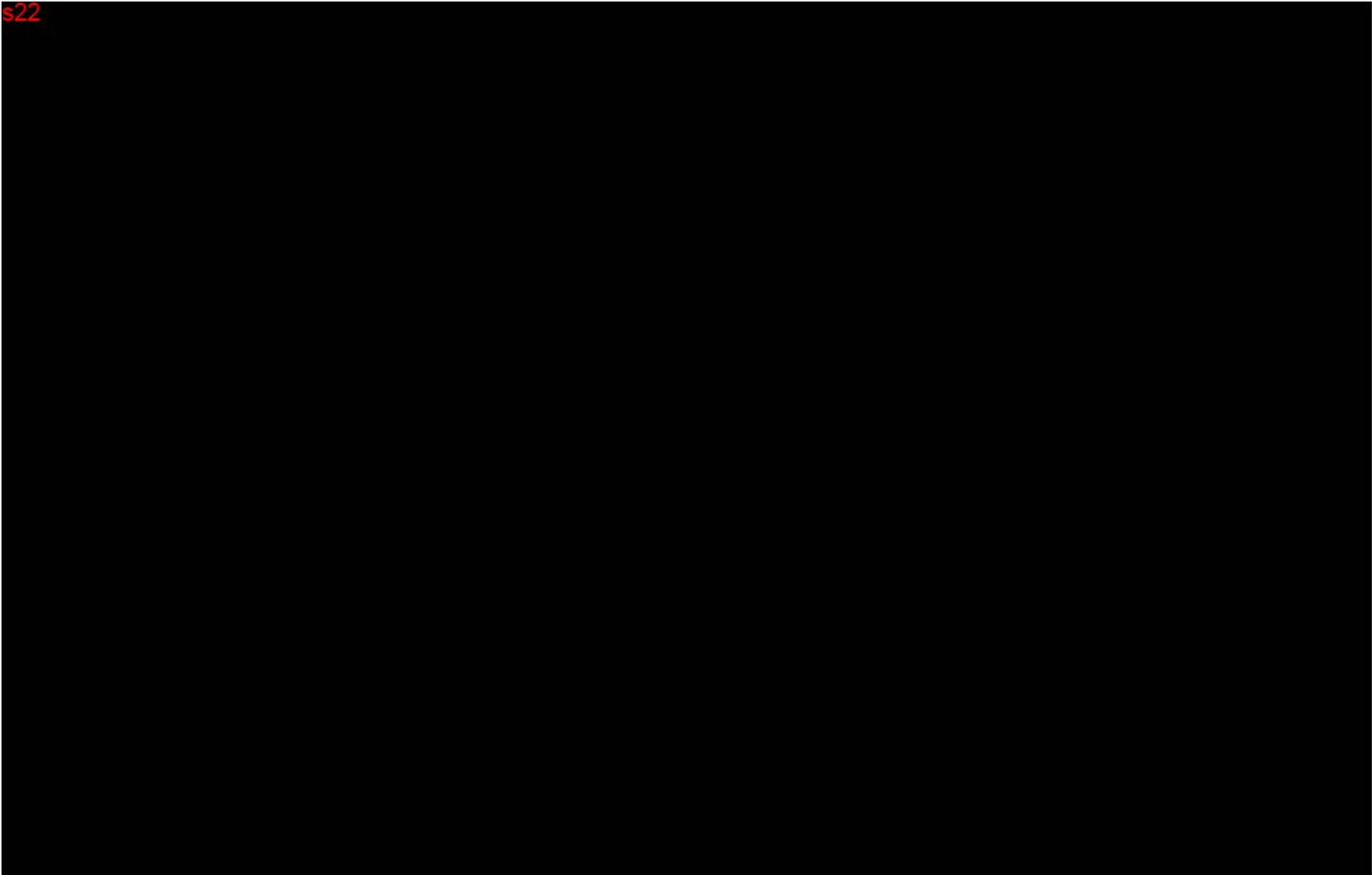


Minutes of the
Adverse Drug Reactions
Advisory Committee

301st meeting

15 June 2007



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 s22 [redacted]..... 56

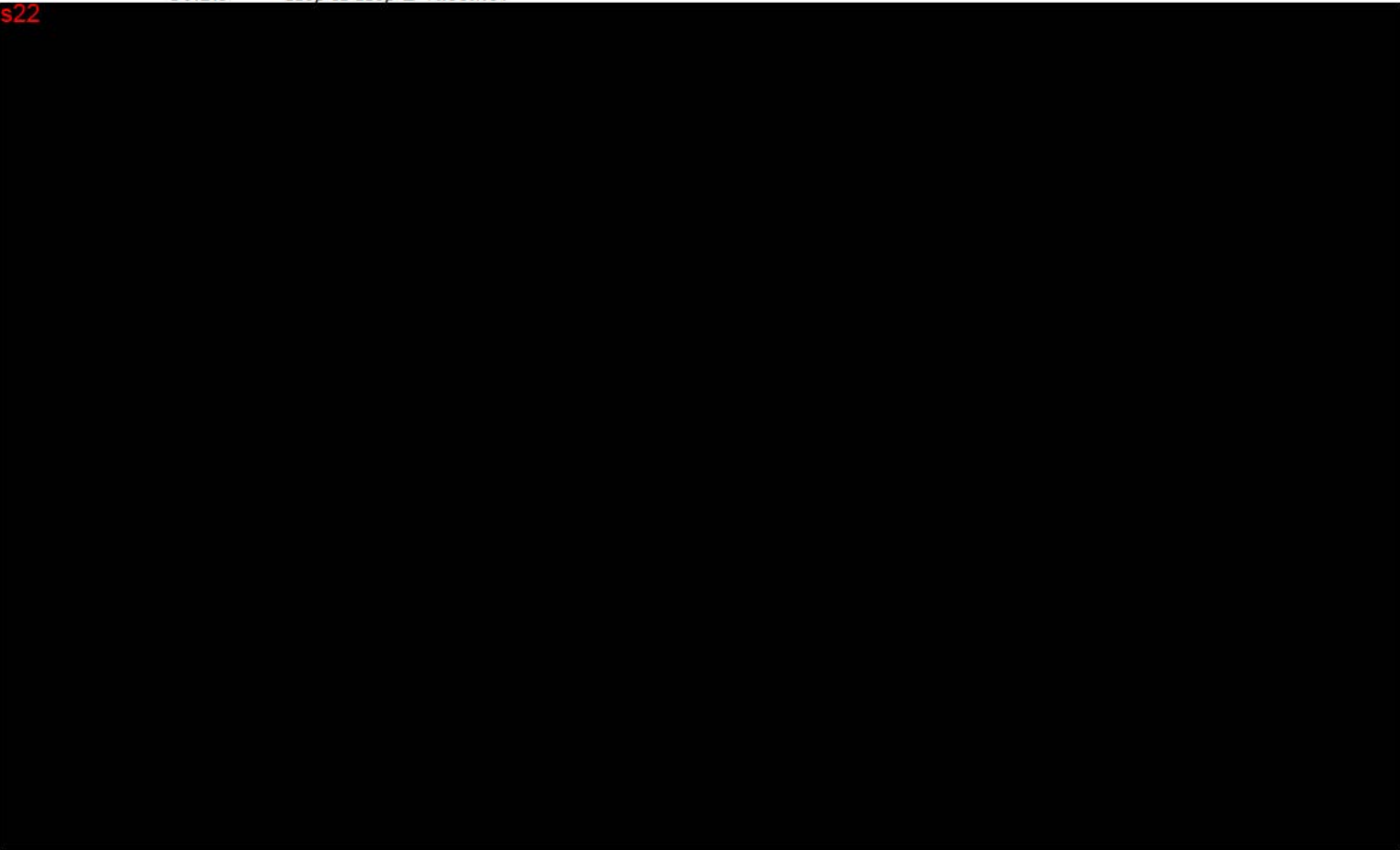
 10.2 VACCINE REPORTS..... 56

 s22 [redacted]..... 56

 10.2.3 *DTPa-IPV-Hib-Hep B vaccine*..... 59

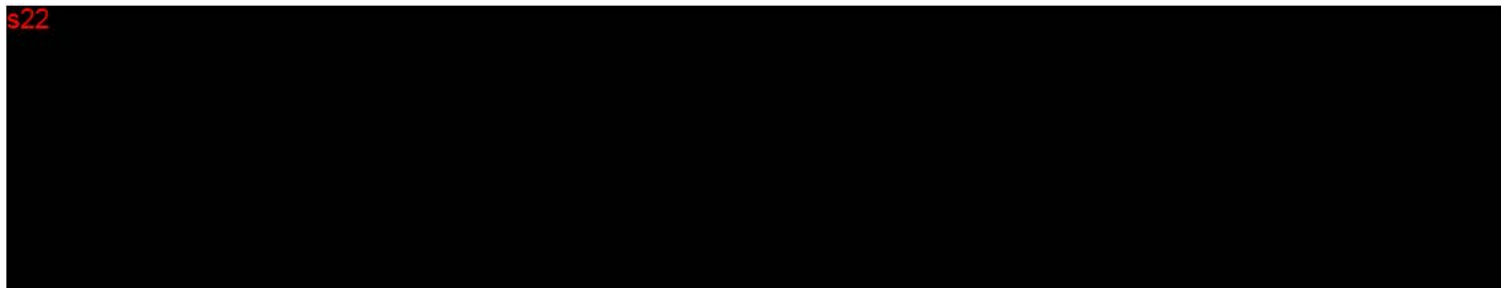
 10.2.4 *Hepatitis B vaccine*..... 59

 10.2.5 *Hep A-Hep B vaccine*..... 59



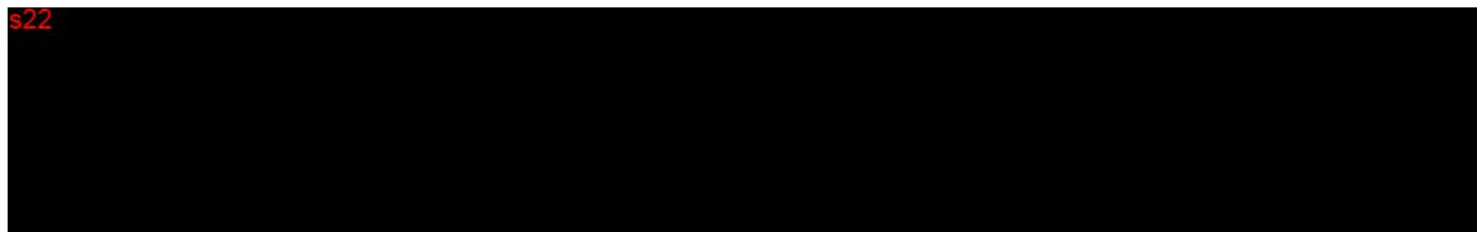
Pages 4-59 redacted under s22 of the FOI Act

s22



10 Vaccines

s22



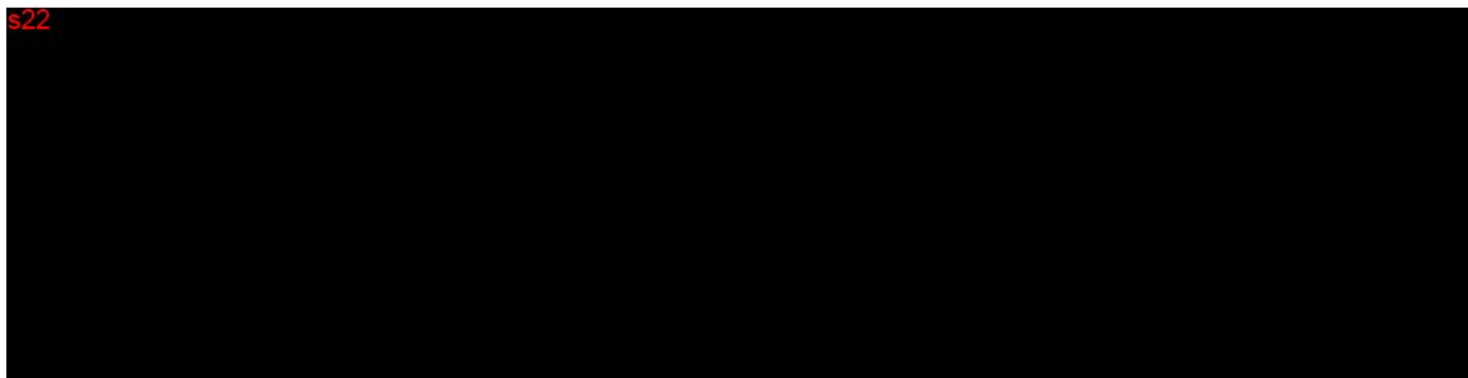
10.2 Vaccine reports

s22



The number of reports associated with each vaccine is shown in the table below along with details of some of the specific reactions described.

s22



Vaccine	No. reports	Inject. site reaction	Convulsion seizure	Fever/pyrexia	Dyspnoea/apnoea	HHE	Notable reports, other important reactions / comments
s22							
DTPa-IPV-HiB-Hep B	4			1		1	Face oedema – s22 HHE - s22
Hepatitis B	6	2					Blurred vision, muscle twitch, periorbital disorder – s22 s22 – peripheral oedema
Hep A-Hep B	1						s22 – balance disorder
HiB-Hepatitis B	2	1	1				s22 – s22
s22							

s22

Report s22

This was a consumer report of a 4 month female infant who received routine vaccination with s22 Comvax and s22. She developed a fever s22 and had a febrile convulsion s22. The pyrexia s22. It may have been too early for febrile convulsion to be due to a response to vaccination.

s22

Report

A female infant vaccinated with Infanrix Hexa and s22 at 8 weeks s22

the

reaction was considered to be hypotonic-hyporesponsive episode, but it was not entirely consistent with the current definition of this disorder, which includes pallor, limpness and unresponsiveness.

s22

10.2.3 DTPa-IPV-Hib-Hep B vaccine

Report

A 6 month old infant developed face swelling

Infanrix Hexa and

Report

A 2 month old female infant given Infanrix Hexa and developed classic hypotonic-hyporesponsive episode, with irritability and pallor.

10.2.4 Hepatitis B vaccine

Report

An 11 year old boy given an adult dose of Hep B vaccine developed a rash around the eyes with blurred vision and facial tics. It was noted that either an adult or paediatric dose can be given to this age group.

Report

An 11 year old girl experienced swelling of the fingers and toes after receiving vaccination with H-B-Vax II and recovered the same day. She was reported to have had a similar reaction to. As with report this was consistent with an allergic reaction to Hep B vaccine.

10.2.5 Hep A-Hep B vaccine

Report

A 39 year old man given Twinrix and developed dizziness, wooziness, nausea, tinnitus flickering of eyes.

10.2.6 Meningococcal vaccine

Report

A 1 yr old girl vaccinated with Hib-Hep B (Comvax), and vaccines developed redness and swelling to the nearest joint.

Pages 64-79 redacted under s22 of the FOI Act