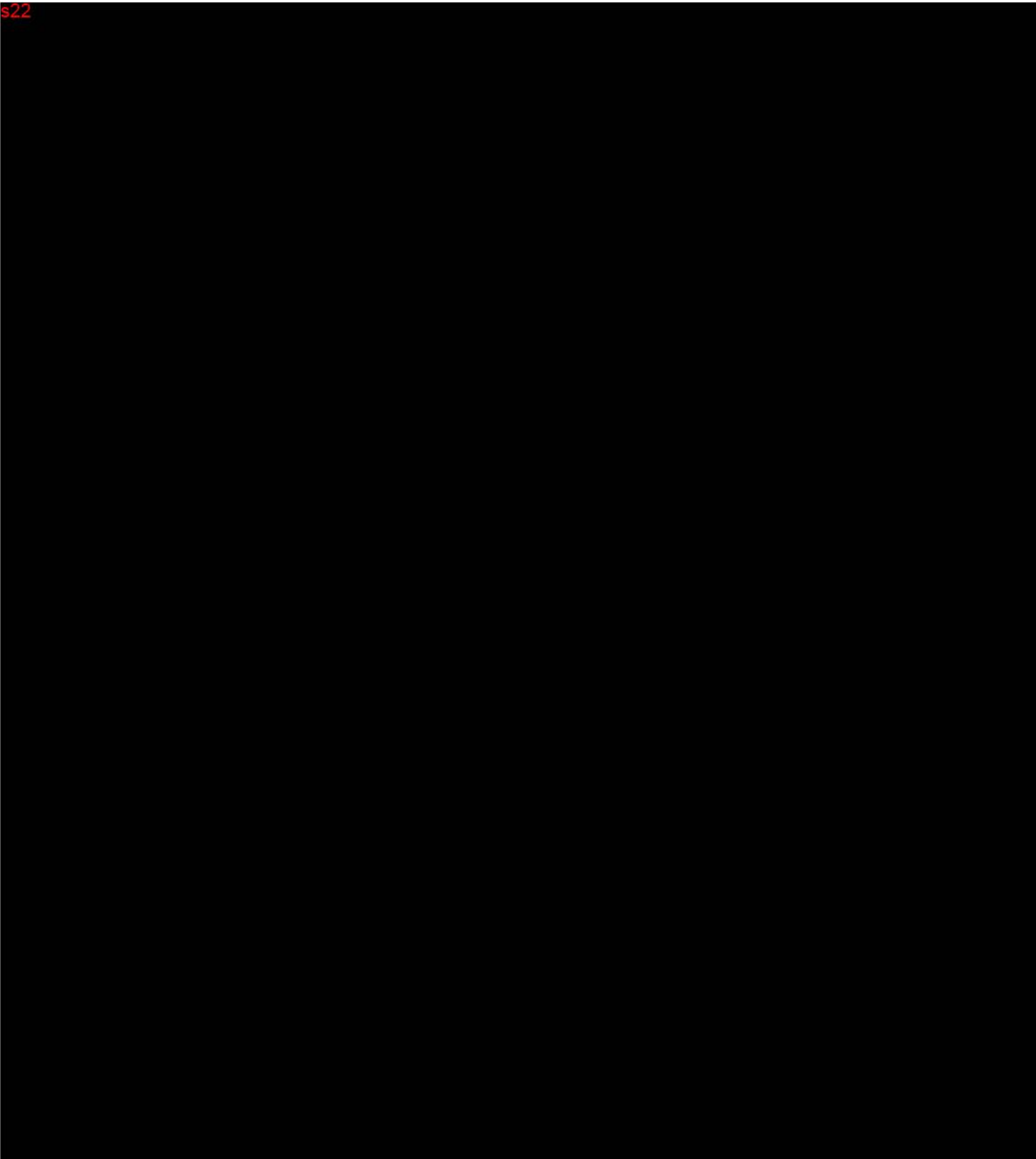


Minutes of the
Adverse Drug Reactions
Advisory Committee

298th meeting

9 February 2007



10 VACCINES.....47

10.2 VACCINE REPORTS.....47

10.2.1 Hep A-Hep B, s22 vaccines and anaphylaxis 50

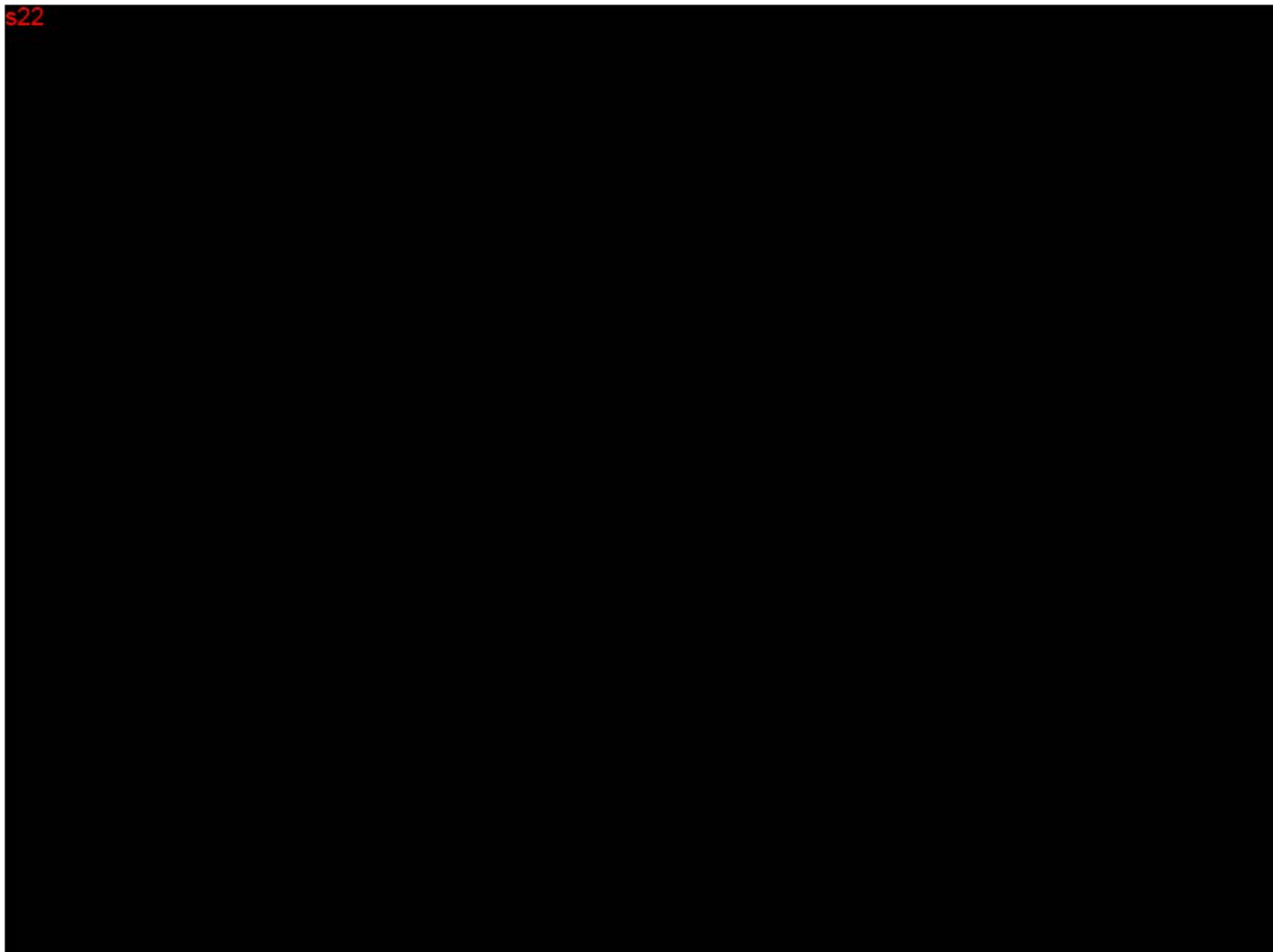
10.2.2 Hepatitis B vaccine and angioedema 50

10.2.3 s22, Hib-Hep B and s22 vaccines and apnoea 50

10.2.5 Hib-Hep B, s22 and s22 vaccines and anaphylaxis 50

Pages 4-50 redacted under s22 of the FOI Act

s22



10.2 Vaccine reports

s22



s22 The vaccines associated with five or more reports were: s22 Hib-Hep B (8), and DTPa-IPV-Hib-Hep B (Infanrix Hexa; 5).

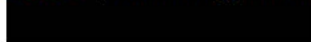
s22



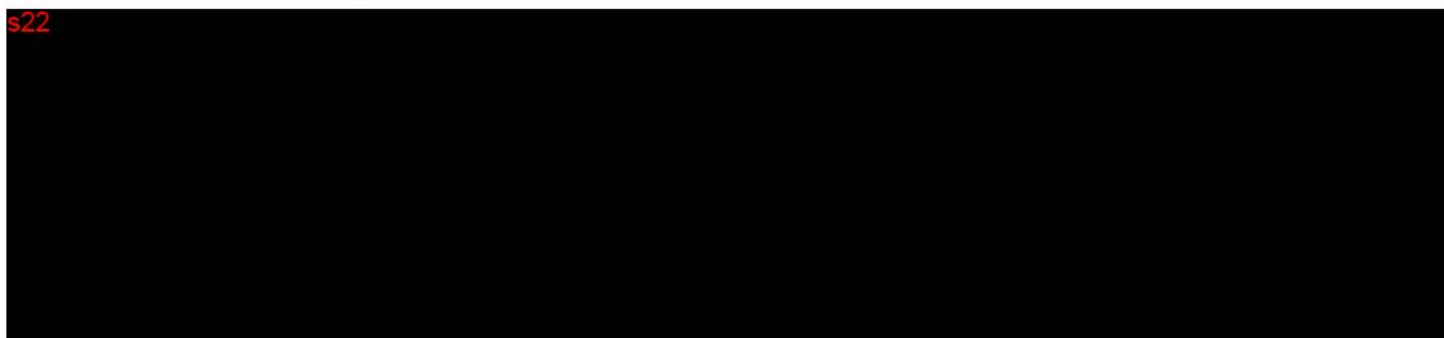
Details of reactions associated with individual vaccines are shown in the Table, below.

s22

s22 2 reports described anaphylaxis (s22 involving Hep A-Hep B, s22 and s22 vaccines; and s22 involving Hib-Hep B, s22 and s22 vaccines); s22



s22



Vaccine	Inject. site reaction	Urticaria /rash /pruritus	Conv- ulsion seizure	Fever/ pyrexia	Dyspnoea/ apnoea	HHE	Other reactions of potential interest / comments
s22							
Hepatitis B							Arthritis reactive (s22 lip swelling, throat irritation, headache (s22
s22							
Hep A-Hep B							1 report (s22 - anaphylaxis
HiB-Hepatitis B	1	4		2	3		3 x anorexia; 2 x lethargy; 2 x irritability; pallor; bradycardia; cyanosis, dysphonia
s22							



10.2.1 Hep A-Hep B, s22 vaccines and anaphylaxis

Report [REDACTED] / [REDACTED]

s22 [REDACTED] In the first sequence, the patient was immunised with Hep A-Hep B, s22 [REDACTED] and adsorbed s22 [REDACTED] vaccines and within 5 minutes she developed burning, itching and swelling at the injection site. One hour later she developed a blotchy rash on her chest and back, felt moderately dizzy and had difficulty breathing with chest tightness.

On a separate date the patient received “the third dose of hepatitis vaccine” and within 10-20 minutes she developed dizziness, urticarial rash and vomiting.

10.2.2 Hepatitis B vaccine and angioedema

Report [REDACTED] / [REDACTED]

This report described two separate sequences in a 14 year old female, but only one of the reactions related to vaccines. In this case, the patient developed itchy throat, headache and mild lip swelling soon after administration of hepatitis B vaccine.

s22 [REDACTED]

10.2.3 [REDACTED], Hib-Hep B and s22 vaccines and apnoea

Report [REDACTED]

This report involved an episode of apnoea and bradycardia following vaccination in a 3 month old baby s22 [REDACTED].

s22 [REDACTED]

10.2.5 Hib-Hep B, s22 and [REDACTED] vaccines and anaphylaxis

Report [REDACTED]

A 1 year child experienced distress, crying, coughing, hoarseness, blue discolouration and wheeze following immunisation with Hib-Hep B, s22 [REDACTED] and s22 [REDACTED] vaccines. s22 [REDACTED]

[REDACTED] This child was treated with adrenaline which was appropriate given the sudden-onset respiratory symptoms.

Pages 55-77 redacted under s22 of the FOI Act