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**OVERVIEW OF COMMENTS RECEIVED ON
THE CORE SPC FOR HUMAN ANTI-D IMMUNOGLOBULIN FOR
INTRAVENOUS USE CPMP/BPWP/319619/2005**

Table 1: Organisations that commented on the draft core SPC as released for consultation

Name of Organisation or individual	Country
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Table 2: Discussion of comments

GENERAL COMMENTS - OVERVIEW		
No external comments were received but adaptations of the text to take into account issues raised internally were made as described below.		
SPECIFIC COMMENTS ON TEXT		
GUIDELINE SECTION TITLE		
Line no. ¹ + paragraph no.	Comment and Rationale	Outcome
		There have been spontaneous reports of severe intravascular haemolysis when anti D has been administered intravenously to Rh(D) positive immune thrombocytopenic purpura (ITP) patients. Haemolysis resulting in death has been reported. Although the core SPC does not cover anti-D immunoglobulin for intravenous use in the treatment of ITP, a reminder about these severe reactions has been included in the notes provided with the core SPC and a short statement on this adverse reaction has been included in Section 4.8.

¹ Where applicable