

## **Guidelines for the Blood Transfusion Services**

### **22.4: Adverse events and reactions**

<http://aws-lon-jpac.targetservers.uk/red-book/chapter-22-haemopoietic-progenitor-cells/22-4>

## **22.4: Adverse events and reactions**

### **22.4.1: HTA Guide for the management of serious adverse events (SAEs) and reactions (SARs)**

All licensed establishments must have a system in place for reporting, investigating, registering and recording information about SAEs and SARs which may influence the quality and safety of tissues and cells, and which may be associated with any licensable activity, as well as any SAR observed during or after clinical application which may be linked to the quality and safety of tissues and cells.

[www.hta.gov.uk/guidance-professionals/regulated-sectors/human-application/hta-guide-quality-and-safety-assurance](http://www.hta.gov.uk/guidance-professionals/regulated-sectors/human-application/hta-guide-quality-and-safety-assurance)

### **22.4.2: WMDA reporting system**

WMDA maintains a voluntary central global reporting system to report Serious (Product) Events and Adverse Reactions – S(P)EARs as below

<https://spear.wmda.info/>