

JOINT SHOT MHRA STATEMENT

THE DEVELOPMENT OF A JOINT UK HAEMOVIGILANCE SYSTEM

The Medicines and Healthcare products Regulatory Agency (MHRA) and Serious Hazards of Transfusion (SHOT) teams have been working towards producing a joint haemovigilance reporting system that is fit for reporters' purposes as well as those of the MHRA and SHOT.

A joint system will:

- provide a fully integrated on-line MHRA and SHOT reporting facility that avoids duplication of reporting for the reporter
- meet the reporters' regulatory requirements for reporting to the UK competent authority (MHRA) all Serious Adverse Reactions (SAR), Serious Adverse Events (SAE) and Corrective and Preventative Actions (CAPA) as defined under the Blood Safety and Quality Regulations (BSQR)
- meet the professionally mandated requirements for reporting to SHOT

Update on progress

Both organisations have agreed to a three phase approach:

- **Phase 1:** Capture and share all SARs reported to MHRA and SHOT – To fix the identified regulatory problem of SAR under-reporting to MHRA.
- **Phase 2:** Design, jointly test and implement a fully integrated on-line joint UK haemovigilance system that incorporates both SAR and SAEs and captures all of the SHOT and MHRA datasets in line with the requirements of the BSQRs and SHOT categorisations.
- **Phase 3:** Investigate the possible development of a means of submitting SAR and SAE reports in line with the agreed Phase 2 dataset (above) from Local Risk Management Systems (DATiX, Ulysses, Q Pulse, etc.) supporting the current MHRA single reporting strategy for medicines and medical devices.

Phase 1 is currently in the later stages of development and is due to be released in October 2015. MHRA and SHOT will be canvassing a selection of reporters in the near future to ensure that the new arrangements meet their needs by reducing duplication and simplifying the SAR reporting process. Reporters will receive an easy-to-follow user guide.

Agreement has been reached to proceed with **Phase 2** after launch of Phase 1. **Phase 3** is more complex and will require further definition with collaboration with both local risk management system manufacturers and reporters.

A new name:

The new joint MHRA and SHOT reporting platform has yet to be named. SHOT and the MHRA therefore are inviting you to suggest a title that reflects the joint nature and the functionality of the platform.