

Guidance Sheet on Blood Serious Adverse Reactions (SARs) Imputability Level

Introduction

It is a legal requirement that any serious adverse reaction (SAR) observed during or after a transfusion which may be attributed to the quality and the safety of blood and blood components is notified immediately to the Medicines Authority (Article 15 Paragraph 1 of Directive 2002/98/EC). The appropriate way of reporting SARs to the Medicines Authority is by completing the Blood Serious Adverse Reaction (SAR) Report Form (which can be downloaded from the Medicines Authority's website www.health.gov.mt/mru).

Completing the Blood Serious Adverse Reaction (SAR) Report Form

In the section titled “Details of Serious Adverse Reaction (SAR)”, the relevant tick box(es) are ticked according to the type of SAR being reported. Furthermore, the Imputability¹ Level for the SAR being reported is determined by the reporting establishment according to the following criteria and filled into the Blood SAR Report Form:

Imputability Levels to Assess SARs:

| Imputability Level | | Explanation |
|--------------------|------------------|--|
| NA | Not assessable | When there is insufficient data for imputability assessment. |
| 0 | Excluded | When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to alternative causes. |
| | Unlikely | When the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood or blood components. |
| 1 | Possible | When the evidence is indeterminate for attributing the adverse reaction either to the blood or blood component or to alternative causes. |
| 2 | Likely, Probable | When the evidence is clearly in favour of attributing the adverse reaction to the blood or blood component. |
| 3 | Certain | When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood or blood component. |

Queries regarding completion of the Blood SAR Report Form can be directed to the staff at the Post-Licensing Directorate during working hours on telephone number 23439153, fax number 23439158 or email address: postlicensing.mru@gov.mt

¹ “Imputability” means the likelihood that a serious adverse reaction in a recipient can be attributed to the blood or blood component transfused or that a serious adverse reaction in a donor can be attributed to the blood donation process.