



Website: <http://www.health.gov.mt>

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DH Circular No. 48/2005

05.04.2005

Re: Serious Adverse Events & Serious Adverse Reactions to Blood and Blood Components

Following the release of Government Notice 99 in The Malta Government Gazette number 17, 716, please be advised that:

- Any serious adverse events related to the collection, testing, processing, storage and distribution of blood and blood components which may have an influence on their quality and safety, as well as any serious adverse reactions observed during or after transfusion which may be attributed to the quality and the safety of the blood and blood components are to be notified to the Medicines Authority;
- Blood establishments¹ and hospital blood banks² shall have procedures in place to notify to the Medicines Authority all relevant information about serious adverse events (SAEs) using the Blood SAE Reporting Form attached at Annex I (which can be downloaded from the Medicines Authority's website on www.health.gov.mt/mru);
- Hospital blood banks, and all other facilities to which blood or blood components may be delivered e.g. hospitals, clinics, manufacturers and bio-medical research institutions, shall have procedures in place to notify to the Medicines Authority all relevant information about serious adverse reactions (SARs) using the Blood SAR Reporting Form attached at Annex II (which can be downloaded from the Medicines Authority's website). The Blood Serious Adverse Reactions (SARs) Imputability Level Guidance Sheet required for the determination of the imputability level of the SAR reported is attached at Annex III and can also be downloaded from the Medicines Authority's website. Moreover, hospital blood banks should send a duplicate Blood SAR reporting form to the blood establishment;

¹ “Blood establishment” is defined as any structure or body structure or body that is responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and their processing, storage, and distribution when intended for transfusion. This does not include hospital blood banks (Directive 2002/98/EC).

² “Hospital blood bank” shall mean a hospital unit which stores and distributes and may perform compatibility tests on blood and blood components exclusively for use within hospital facilities, including hospital based transfusion activities (Directive 2002/98/EC).

DIVIZJONI TAS-SAHHA

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- Stakeholders have a derogation of nine months from 8 February 2005 to implement all the necessary requirements to comply with Directive 2002/98/EC as stated in article 7 of the latter Directive.
- In the case of medicinal products containing blood components, the same Adverse Drug Reaction (ADR) reporting system as for other medicinal products should be used. Further information on the ADR reporting system and the ADR reporting form used for reporting suspected ADRs on medicinal products can be obtained from the Medicines Authority's website.

Dr Ray Busuttil
Director General (Health)



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Annex I: Blood Serious Adverse Event (SAE) Reporting Form

AWTORITA DWAR IL-MEDICINI - MEDICINES AUTHORITY
198, Rue D'Argens, Gżira GZR03
Tel: 23439133 Fax: 23439138
Email: postlicensing.mra@gov.mt



BLOOD SERIOUS ADVERSE EVENT (SAE) REPORT FORM

ALL CONSUMER/PATIENT AND REPORTER INFORMATION WILL REMAIN CONFIDENTIAL

Please complete as much information as possible. Do not be put off reporting if some details are not known.

REPORT IDENTIFICATION NUMBER OF REPORTING ESTABLISHMENT:				
DETAILS OF SERIOUS ADVERSE EVENT (SAE)				
Date of SAE (DD/MM/YYYY):				
Serious Adverse Event (SAE) which may affect quality and safety of blood component due to a deviation in:	Specification			
	Product defect	Equipment failure	Human Error	Other (please specify)
Whole blood collection				
Apheresis collection				
Testing of donations				
Processing				
Storage				
Distribution				
Materials				
Others				
REPORTING ESTABLISHMENT				
Type (please circle): blood establishment, hospital blood bank				
Name:				
Address:				
Telephone/Mobile:				
E-mail address:				
Signature _____			Date of Report _____	
An electronic version of the SAE report form can be downloaded from: www.health.gov.mt/mra			☐ SUPPLY OF SAE REPORT FORM IS REQUIRED	



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Annex II: Blood Serious Adverse Reaction (SAR) Reporting Form

AWTORITÀ DWAR IL-MEDICINI - MEDICINES AUTHORITY

Post-Licensing Directorate

198, Rue D'Argens, Gżira GZR03

Tel: 23439153 Fax: 23439158

Email: postlicensing.mru@gov.mt**BLOOD SERIOUS ADVERSE REACTION (SAR) REPORT FORM****ALL CONSUMER/PATIENT AND REPORTER INFORMATION WILL REMAIN CONFIDENTIAL**

Please complete as much information as possible. Do not be put off reporting if some details are not known.

REPORT IDENTIFICATION NUMBER OF REPORTING ESTABLISHMENT:

RECIPIENT DETAILS (Please tick or record details accordingly)

INITIALS _____ SEX MALE FEMALE AGE (at time of SAR) _____ WEIGHT (in kg, if known) _____
ETHNICITY _____ AREA _____

TYPE OF BLOOD/BLOOD COMPONENTS (Please tick accordingly)

Batch number of blood/blood component

<input type="checkbox"/> Whole blood	
<input type="checkbox"/> Red Blood Cells	
<input type="checkbox"/> Platelets	
<input type="checkbox"/> Plasma	
<input type="checkbox"/> Albumin	
<input type="checkbox"/> Immunoglobulin	
<input type="checkbox"/> Other (please specify)	

DETAILS OF SERIOUS ADVERSE REACTION (SAR)

Date of Transfusion (DD/MM/YYYY): / /	Time of Transfusion: a.m. / p.m.	
Date of SAR (DD/MM/YYYY): / /	Time of SAR: a.m. / p.m.	
Amount transfused: ml	<input type="checkbox"/> <¼ <input type="checkbox"/> <½ <input type="checkbox"/> <¾ <input type="checkbox"/> >¾ (please tick accordingly)	
Type of SAR (please tick accordingly):	Imputability Level* Type of SAR (please tick accordingly): Imputability Level*	
<input type="checkbox"/> Immunological haemolysis due to ABO incompatibility	<input type="checkbox"/> Transfusion-transmitted viral infection (HIV-1/2)	
<input type="checkbox"/> Immunological haemolysis due to other all-antibody	<input type="checkbox"/> Transfusion-transmitted viral infection, Other (please specify)	
<input type="checkbox"/> Non-immunological haemolysis	<input type="checkbox"/> Transfusion-transmitted parasitological infection (Malaria)	
<input type="checkbox"/> Post-transfusion bacterial infection	<input type="checkbox"/> Transfusion-transmitted parasitological infection, Other (please specify)	
<input type="checkbox"/> Transfusion-related acute lung injury	<input type="checkbox"/> Graft versus host disease	
<input type="checkbox"/> Transfusion-transmitted viral infection (HBV)	<input type="checkbox"/> Other SAR(s) (please specify)	
<input type="checkbox"/> Transfusion-transmitted viral infection (HCV)		

REPORTING ESTABLISHMENT

Type (please circle): hospital blood bank, hospital, hospital, clinic, manufacturer, bio-medical research institution
Name:
Address:
Telephone/Mobile:
E-mail address:

Signature _____ Date of Report _____

An electronic version of the SAR report form can be downloaded from: www.health.gov.mt/mru SUPPLY OF SAR REPORT FORM IS REQUIRED

*Please mark NA, 0, 1, 2, 3** accordingly

** Refer to Blood Serious Adverse Reactions (SARs) Imputability Level Guidance Sheet for determination of the imputability level.

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Annex III: Blood Serious Adverse Reactions (SARs) Imputability Level Guidance Sheet



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.