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MEETING OF THE SOHO VIGILANCE EXPERT SUB-GROUP

7 APRIL 2017

DG SANTE, BRUSSELS

DRAFT MINUTES

Participants:

19 Member States were present, as well as representatives from the Council of Europe, the VISTART Joint Action work packages on vigilance and DG SANTE unit B4.

The meeting was chaired by DG SANTE.

1. Introduction and background

This was the first meeting of the newly formed SoHO Vigilance Expert Sub-group (a sub-group of the Expert Group CASoHO E01718). The group replaces the previous Haemovigilance Expert Sub-group.

It was clarified that this Sub-group shall provide technical expertise to the Commission in the following areas:

a. Annual reporting by Member States to the Commission on Serious Adverse Reactions and Events (SARE) associated with blood, tissues and cells, the improvement of the Common Approach for definition of reportable SARE and on the analysis and publication by the Commission of annual summaries of the Member State country reports.

b. Rapid Alert platforms Blood (RAB) and Tissues&Cells (RATC).

c. Other vigilance and surveillance activities.

The full mandate of the Sub-group is laid down in the Terms of Reference (ToR), which had been agreed with the SoHO Expert Group meetings of National Competent Authorities on Blood and on Tissues&Cells respectively.[1]

The Sub-group agreed on the agenda of the meeting.

[1] The ToR was discussed with the SoHO Expert Group meetings of NCA's on Organs on 4 April 2017.

2. Context of the meeting

While the ToR lays down the objectives of the Sub-Group, SANTE also clarified that the timing of this work is important as the outcomes might be important inputs on related Commission activities:

- The ongoing evaluation of the legal frameworks on blood, tissues and cells[2]. Outcomes of this meeting might be useful inputs on vigilance for this evaluation.
- Work within work-packages 4 and 5a of the VISTART Joint Action. The Coordinators of these work-packages were present in the meeting.
- Work by the Council of Europe's EDQM who are contracted to perform the annual data collection, compilation and analyses of national SARE data on behalf of SANTE, with effect from 2017 (2016 data).

3. Key objectives and structure of the meeting

Given the context described above, this meeting was organised as a brainstorm where the many ways in which SARE data collection, analysis and reporting at the EU level might be improved.

The outcome of the meeting would be a list of topics that can be acted upon or that may need further reflection. The list will form the basis of a work plan aimed at improving the quality of SARE reporting for blood, tissues and cells.

It was acknowledged that it may be possible for some topics/improvements to be made in the short-term, when they involve only improving guidance and instructions – particularly in the Common Approach documents provided to competent authorities by the Commission to support them in completing their annual SARE submission to the Commission.

Other topics may require changes to the way data is collected and the template used for submission; these will involve more planning and will take longer.

Importantly, topics with consensus on improvements that would require a change in legislation will be documented in these minutes, which can be used as evidence in the ongoing Evaluation of the legal frameworks on blood, tissues and cells.

4. Discussion

The issues for potential clarification and improvement were grouped in advance into major categories. Following categories were covered:

1. SAR definitions and categories
2. SAR denominators
3. Recipient deaths
4. SAR reporting criteria
5. Severity Assessment SAR

[2] https://ec.europa.eu/health/blood_tissues_organs/policy/evaluation_en

6. Imputability Assessment SAR
7. SAR in donors
8. SAE definitions and categories
9. SAE denominators
10. SAE reporting criteria
11. Other

For each category, key questions were presented by DG SANTE and the discussion was continued by the leaders of Work-package 4 of the VISTART joint action (Portugal) who summarised the thoughts and suggestions of their working groups. This was followed by comments from the EDQM team, arising from their experiences of analysis of SARE data from both the blood and tissue and cell sectors. A general open discussion took place where all participants were invited to make their suggestions for improvements under that category.

Many topics were highlighted that need further in-depth reflection beyond this exploratory meeting. At the close of the meeting, participants were asked to indicate the topics/proposals with a high level of priority for them.

Key topics and messages that were brought forward are:

- There was a consensus that SAR in donors should be reportable regardless of the impact on the quality and safety of the substance donated.
- For ART, SAR should be reported when they concern offspring born following gamete or embryo donation in the SAR definition, as well as when they concern mothers.
- SAR categories should be further specified per SoHO category.
- Specifications were suggested for the SAR denominators for all SoHO types, but in particular there was support to use 'cycles' as denominator for SAR in reproductive T&C.
- As for blood, reporting of deaths in recipients should be mandatory for T&C, whenever they take place within a certain interval following application of T&C.
- Fungal infections are to be added as new SAR category of transfusion transmitted infections for both blood and T&C.
- As for blood, SAR imputability should be defined for Tissues, cells and ART.
- Many SAE are reported as 'human error', for which reporting is to be further broken down in sub-categories.
- The donor selection step should also be included in the SAE reporting scope.
- To encourage and improve reporting of SAREs within each member state and to the Commission.

5. Closing of the meeting

SANTE expressed gratitude for the active participation and inputs. They also highlighted that the key topics brought forward and issues identified will serve as inputs for the work on VISTART WP4, CoE/EDQM annual SARE data collection and for the public consultation of the evaluation.

Rapporteurs will be appointed to act on behalf of this expert sub-group in the future, e.g. to assist in developing a work plan, taking forward prioritized ideas/actions from the meeting, coordinate the collaboration of the participants of the vigilance Expert sub-group. A rapporteur will report back on progress to the blood NCA meeting and the tissues and cells NCA meeting.

SANTE thanked for the good spirit in which the experts started the work of this sub-group.