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Vigilance Expert Subgroup (VES) of the National Competent Authorities (NCA) for Substances of Human Origin Expert Group

2022 VES ANNUAL REPORT

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1. EXECUTIVE SUMMARY

In 2022 the CASoHO were invited to (re)nominate their expert representatives in the VES, which at the end of 2022 had some 90 members from 24 EU member states. Five VES rapporteurs coordinate the VES work and ensure that the Commission's services are informed of VES activities and recommendations.

In 2022 the VES assisted in preparing the annual SARE reporting exercise for blood and for tissues and cells, which was conducted using a web reporting form replicating the functionalities of the previous pdf template. The Common Approach guidance documents for blood and for tissues and cells SARE reporting were updated to incorporate technical instructions for use of the webforms.

The VES work in 2022, as in previous years, was conducted in working subgroups (SARE reporting improvement, RAB/RATC, Organs, VES-IES collaboration). A plenary online VES meeting was held in December 2022.

At the request of the Commission's services, the VES prepared a voluntary pilot of EU submission of Organs SARE and activity data collected in 2022 at national level. The reporting exercise will be conducted in 2023.

Members of the VES met with representatives of the Inspections Expert Subgroup (IES) and provided input relating to vigilance for the IES inspections guidance.

A group assisted in pre-testing the Rapid Alert systems for Blood and for Tissues and Cells prior to a planned migration and will further review and advise on RAB/RATC functionalities in 2023.

2. INTRODUCTION TO THE VES

The Competent Authorities on Substances of Human Origin (CASoHO) Expert Group agreed with the Commission's services in 2017 to establish an Expert Sub-Group on Vigilance of Blood, Tissues and Cells, referred to as the 'VES'. In 2018, the mandate of the VES was extended to cover organs. VES members are nominated by the National Competent Authorities (NCA) to be their representatives for vigilance relating to blood, tissues and cells (including medically assisted reproduction) and organs.

The aim of the subgroup is to provide technical expertise to the Commission's services in relation to the conduct of the annual reporting by Member States to the Commission on Serious Adverse Reactions and Events (SARE) associated with blood, tissues and cells, and all its vigilance-related activities including the domain of organs. Work is performed in working subgroups of the VES, with wider consultation of the whole VES as and when necessary. A group of rapporteurs, proposed from within the VES and appointed by the Commission's services, coordinates the activities and organises an annual meeting of the VES. The rapporteurs also ensure that the National Competent Authorities are informed of the VES activities.

All VES guidance documents are submitted to the CASoHO for their endorsement.

In October 2022 the Blood, Tissues/Cells and Organs national competent authorities were invited to reconfirm their experts or nominate new or additional experts to represent them in the VES. As a result, the VES membership grew from approximately 50 members from 21 member states (including UK and Iceland) to approximately 95 from 24 member states (including Iceland).

In 2022, the VES working subgroups were as follows:

- SARE reporting improvement
- RAB/RATC review
- VES and IES cross-fertilisation
- Organs.

3. ACTIVITIES IN 2022

In 2022 the VES for the first time followed an annual work programme which was submitted for approval to the members and NCA and adopted. A formal report on activities in 2021 was published on the Commission website. The VES activities in 2022 were conducted through email exchanges and working meetings using online meeting platforms. A plenary VES meeting was held (online) in December 2022. The VES Terms of Reference were circulated to all the VES members with a view to finalization of the consolidated text and formal adoption by the NCA in 2023. Activities in the VES working subgroups are described below.

Following the publication of the proposed Regulation for Substances of Human Origin (SoHO) in July 2022 the VES analysed the outcome with respect to its 2021 recommendations in the domain of vigilance, the "VES wish list". This analysis, to which the rapporteurs and several members of the wider VES contributed, was provided to the Commission's services in a response through the Have Your Say portal in September 2022 and circulated among the VES members.

4. VES WORKING SUBGROUPS

4.1. Subgroup for SARE reporting improvement

This working subgroup of the VES provided technical expertise in preparing the SARE reporting exercises for Blood and for Tissues and Cells in 2022 (collection of 2021 data) which for the first time was conducted using webforms. Subgroup members assisted the Commission's services by testing the webforms. Notable changes for Tissues and Cells reporting were the separation of the non-reproductive sector into haematopoietic stem cells and replacement tissues, and collection of serious adverse reactions according to the assigned imputability. The "Common Approach" guidance documents for Blood and for Tissues and Cells were updated to incorporate user instructions for the webforms and checked by subgroup members. Overall, the 2022 SARE reporting exercise was reported to have run smoothly; minor issues will be taken into account in preparing the 2023 exercise.

Following addition of new members, a subgroup meeting was held in December 2022. At the time of the December VES meeting the preliminary analyses by EDQM of the 2023

SARE reporting exercise were not yet available for review and advice by the VES members.

The proposed SoHO Regulation will bring changes in the domain of vigilance, and the VES will develop a phased programme to prepare for their implementation in the coming years.

Within the SARE reporting improvement subgroup a wide (100-fold) difference in rate of reported blood donor serious adverse reactions has been noted and ascribed primarily to differences in assessment of seriousness of reactions. Such differences in rates are an impediment to comparisons and learning from the EU-level data. Prior to the COVID-2019 pandemic an international tool to support harmonization of seriousness assessment was published and endorsed by the European Blood Alliance. A voluntary pilot of (parallel) data collection of blood donor SAR data using the tool has been agreed to in consultation with the NCA. Materials and an invitation letter for each NCA to inform their blood establishments were provided in preparation for the SAR assessments in 2023.

4.2. RAB/RATC review

This working subgroup of the VES was launched in 2021 to review of the Rapid Alert system for Blood and for Tissues and Cells (RAB/RATC) and has highlighted a need for training materials for users. An initial small improvement (possibility of immediate closure if no further information will be forthcoming) was implemented in 2022. A meeting was held with the new members in November 2022 and members contributed to testing prior to the migration of the RAB/RATC system to the new platform.

4.3. VES and IES cross-fertilisation

This new VES working subgroup was launched in July 2021 for collaboration, cross-fertilisation and mutual support between the VES and the Inspections Expert Subgroup (IES). Activity in 2022 was focused on providing VES input to a chapter relating to vigilance in the Inspections guidance, which is under revision by the IES. The subgroup met with IES members in February 2022 and progressed their contribution through email contacts and three online meetings. A matrix of points for inspection based on outputs of the major previous projects EUSTITE, SoHO V&S and VISTART was worked on to support this. As of December 2022, VES review of the draft IES text was in progress.

In the autumn of 2022 new members joined this working subgroup. An area highlighted for future attention is to review the existing IES code of practice for joint inspections, in anticipation of possible future peer review and EU audit of vigilance activity at member state level.

4.4. Organs

As discussed in previous years within the VES, reporting of Organs SARE is currently mandated in member states but no data are collected by the Commission's services. A voluntary pilot of EU-level submission of the national-level information was announced to the Organs NCA in 2021. The Organs working subgroup of the VES provided the proposed data tables and a basic guidance document for the pilot to the NCA at the beginning of 2022; the pilot is focused on SARE of clearcut types. Clarifications were given at the NCA meeting in June. The VES Organs working subgroup was strengthened by new nominations in October 2022 and met in November. A proposed survey on the state of Organs vigilance is being developed to inform the NCA and the Commission's services; the survey will be sent to all the Organs NCA at the time of the pilot data collection. Data collection is planned for the first quarter of 2023.