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

2023 VES ANNUAL REPORT

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1. 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 to be their representatives on blood, tissues and cells (including medically assisted reproduction) and organs. Representatives of the EDQM and ECDC teams participate in VES as experts. As of December 2023, the VES had approximately 95 nominated members.

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. 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 deliberations.

In 2023 the VES working subgroups were as follows:

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

2. ACTIVITIES IN 2023

In 2023 the VES took stock of the situation regarding the annual blood and tissue/cell (B and T/C) SARE collection exercises using the recently (2022) introduced webforms and successively refined B and T/C "Common Approach" guidance, user experiences of the RAB/RATC system and the forthcoming changes under the proposed Regulation for Substances of Human Origin (to be finalised in the definitive text when published). Two online meetings followed by an in-person workshop were held in the spring with a focus on optimizing the B and T/C SARE exercises and their analyses, leading to a work list of proposed items to be considered and prioritised for the coming years. Activities undertaken by the VES working subgroups are described further below. The annual VES meeting took place in December 2023. In the spring and the autumn meetings, EDQM representatives gave presentations of the results of the 2021 and 2022 SARE reporting exercises. Feedback and discussion within VES should contribute to further refining the analysis and reporting on the annual exercises.

The VES activities were coordinated by the group of rapporteurs. In 2024 and the coming years the VES internal organization should be reviewed and strengthened to prepare for the new phase as an expert group under the future SoHO Coordination Board

3. VES WORKING SUBGROUPS

3.1. Subgroup for SARE reporting improvement

This working subgroup (with approximately members) of the VES provided technical expertise in preparing the SARE reporting exercises for B and for T/C in 2023 (collection of 2022 data) which as in recent years were conducted using the purpose-built Blood and Tissues/Cells webforms. The B and T/C "Common Approach" guidance documents for the reporting were updated with minor revisions.

At the May 2023 online VES meeting, EDQM representatives presented summary results of the 2021 reporting exercise which were also circulated in more extended form prior to the meeting. EDQM and VES members discussed challenges from suboptimal quality data limiting analyses, and specific items were noted for further discussion and possible future improvements. In addition, the proposed future denominators for the annual SARE exercise (a subset of the tissues and cells harmonized activity dataset which was developed

in the project led by EDQM in 2018-2020) should be further discussed within VES and their implementation prepared by VES or within dedicated EU projects (e.g. EUMAR).

In June approximately 35 VES members and experts participated in a face-to-face workshop which initiated the prioritisation of SARE reporting improvement items, with a proposed subdivision into clusters. The members of the VES SARE improvement working subgroup were invited to express interest in working on the clusters:

Recipient SAR

Donor protection

MAR offspring

SAE

General aspects and denominators

A further (online) meeting with discussion in breakout sessions was held in the autumn. A team of volunteers subsequently initiated work on (minor) revisions of the Blood and Tissues/Cells Common Approach guidance in preparation for the 2024 SARE reporting exercise.

In addition, in 2023 the blood competent authorities were provided with relevant information about the planned pilot evaluating an international, European Blood Alliance-endorsed tool for the seriousness assessment of blood donor adverse reactions. Blood donor SAR are submitted annually on a voluntary basis, and currently show a wide range in incidence based on national-level application of the SAR definition from the legislation. The voluntary pilot collection of data using the tool will be held in 2024 (data from 2023), aiming to evaluate whether it will yield more homogeneous data.

An EU-funded project conducted by EDQM, aiming to strengthen biovigilance systems was launched in September 2023. The project is focused primarily on the tissue establishments and professionals whereas VES acts for and advises the competent authorities on vigilance and its use in oversight. VES was informed about the project and a number of VES members are among the core group which attended the kick-off meeting.

3.2. 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) to increase user-friendliness and quality in line with recommendations which were previously made in the VISTART project. Some small improvements (simplifications) have been implemented and the subgroup has initiated revision of the Blood and Tissues/Cells SOPs following the migration (December 2022) of the RAB/RATC system to a new platform. A need for training materials for users has been highlighted.

3.3. VES and IES cross-fertilisation

In 2022 and early 2023 the working subgroup dedicated to VES-IES cross-fertilisation provided input to the chapter relating to vigilance in IES inspections guidance which was under revision.

No meetings of this VES working subgroup were held in 2023, pending designation of cluster leaders within IES and discussion partners for the cross-fertilisation activities. The IES informed VES about the SIGHTSoHO training project for inspections. VES rapporteurs contributed by reviewing vigilance-related materials and will provide tutors for relevant activities in 2024. Also numerous VES members registered as participants and took part in the training modules which commenced in the autumn of 2023.

3.4. Organs

The reporting of Organs SARE data in member states is currently mandated but hitherto no data have been collected by the Commission’s services. Following preparation and advance announcements by the VES Organs working subgroup in 2021 and 2022, a voluntary pilot of organs SARE data collection (data from 2022) was conducted in the spring of 2023, accompanied by a survey on the organs vigilance arrangements in the member states. Organs SARE and denominator data were received from 15 member states and survey information from 21. The data show an encouragingly low rate of serious adverse reactions (0.5% per deceased donor organ transplanted). The organs working subgroup provided feedback to the organs competent authorities in the autumn and proposed a further pilot in 2024 accompanied by data submission guidance based on the 2023 experience and feedback.