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

2021 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 put forward by the National Competent Authorities to be their representatives on 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. 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 2021 the VES working subgroups were as follows:

- SARE reporting improvement
- RAB/RATC review
- VES and IES cross-fertilisation
- Organs
- (Short-term) subgroup for input in legislation revision.

2. 2021 ACTIVITIES

The VES in 2021 contributed in a targeted way to the ongoing revision of the blood, tissues and cells legislation. In the first months, with consultation of the members, a "VES wish list" was developed highlighting areas in relation to vigilance and the SARE reporting which are important to address in the revision. Several of the highlighted wishes were aimed at retaining and anchoring the improvements that have already been brought about in a voluntary way, such as the submission of donor SAR in the annual data collection exercise. The VES wish list was provided to the Commission's services in the Impact Assessment consultation in April 2021. VES representatives participated in relevant workshops and in some cases gave presentations. A short-term VES working subgroup reviewed the "Wish list" items and made recommendations as to the policy options under which they could be implemented. Available members also participated in

an information-gathering interview about costs relating to vigilance and oversight under proposed future legal requirements.

In communication with VES members and stakeholders, a proposed minimum dataset for monitoring blood and blood component activity in the member states was developed and provided to the Commission's services. The proposed minimum dataset aims to provide data, collected according to common definitions, to give a transparent picture of this activity and to provide appropriate background data (denominators) for the annual collection of SARE data.

Activities undertaken by the separate VES working subgroups are listed below. An update meeting for all VES members was held in July 2021 and the annual VES working meeting took place in December 2021. At these two meetings, EDQM representatives gave presentations of the results of the 2019 and 2020 SARE reporting exercises; VES members provided feedback and suggestions to EDQM following these presentations.

3. VES WORKING SUBGROUPS

3.1. 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 2021 (collection of 2020 data) which as in previous years was conducted using a pdf reporting template. The "Common Approach" guidance documents for Blood and for Tissues and Cells reporting were updated with minor revisions.

The Commission's services are preparing a web form for future SARE reporting exercises. The subgroup assisted in checks of the specifications and will contribute to testing and updating of guidance documents in readiness for the 2022 exercise.

At the two VES meetings, EDQM representatives presented the results of the harmonisation exercise for developing a dataset for tissues and cells, including medically assisted reproduction. In the harmonisation exercise, proposals were made for future denominators for the annual SARE exercise. Consideration of these proposals for future use should be addressed by the working subgroup in future.

3.2. RAB/RATC review

This new working subgroup of the VES commenced a 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. Initial small points for improvement were discussed. Work will continue in alignment with the planned migration of the RAB/RATC system to the future platform.

3.3. VES and IES cross-fertilisation

This new working subgroup was launched in July 2021. Activities were proposed for cross-fertilisation and mutual support:

- VES members to review chapter relating to vigilance in Inspections guidance which is currently under revision.
- Review IES code of practice for joint inspections, with a view to developing guidance for possible future peer or EU audit of vigilance activity at member state level.

In a second explorative meeting attended by Inspections Expert Subgroup (IES) members further possible collaborative actions were suggested which will be discussed further in 2022.

3.4. Organs

As discussed in previous years within the VES, reporting of Organs SARE data is currently mandated in member states but no data are collected by the Commission's services. The Organs working subgroup met six times in February – November 2021 and with a chief focus on preparing a voluntary pilot of EU level SARE submission. This proposal was presented to the Organs NCA in November 2021. Data on SARE of clear-cut types in 2022 will be requested 2023. The proposed data tables and a basic guidance ("Common Approach") document for the pilot will be provided to the NCA at the beginning of 2022.