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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Medical Products and Innovation
Medical Products: Quality, Safety, Innovation

INSPECTION EXPERT SUBGROUP (IES) 2023

Annual Report

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1. INTRODUCTION TO THE IES

The Commission Expert Sub-Group on Inspections in the Blood and Tissues & Cells Sectors (IES) is a sub-group of the Competent Authorities on Substances of Human Origin (CASoHO) Expert Group and was established by this group in November 2018, based on Terms of Reference agreed by the expert group.

The IES is designed to help bring further alignment across the EU on inspection-related activities and provide a platform for EU-level collaboration on such activities. However, participation in its work and use of its outputs is voluntary in nature.

2. 2023 IES ACTIVITIES

From 2021 until May 2023, the activities for most Work Clusters had been reduced. Due to the COVID pandemic, face to face meetings were cancelled and the activities that took place were related to the update of the Inspector's guidelines (Work Cluster 1) and the training of inspectors (Work Cluster 2).

In May 2023 a coordinator for the IES has been appointed, and the list of members has been updated. At the end of 2023, 17 MS had appointed representatives to the IES.

Countries with representatives	Countries without representatives
Austria (AT)	Croatia (HR)
Belgium (BE)	Czechia (CZ)
Bulgaria (BG)	Denmark (DK)
Cyprus (CY)	Estonia (EE)
Finland (FI)	Germany (DE)
France (FR)	Hungary (HU)
Greece (EL)	Latvia (LV)
Ireland (IE)	Malta (MT)
Italy (IT)	Slovakia (SK)
Lithuania (LT)	
Luxembourg (LU)	
Netherlands (NL)	
Poland (PL)	
Portugal (PT)	
Slovenia (SI)	
Spain (ES)	
Sweden (SE)	

2.1. IES meeting

On 23 October 2023, DG SANTE hosted the sixth meeting of the Commission Expert Sub-Group on Inspections in the Blood and Tissues & Cells Sectors, which was attended by IES members from Italy, Nederland, Luxemburg, Austria, Slovenia, France, Belgium, Spain, Bulgaria, Finland, Portugal, Lithuania, observer from EDQM and expert from Austria. The meeting was the opportunity for IES members to reconvene together and discuss about priorities and actions within each work cluster, which remain as defined in 2019:

1. Guidance documents;
2. Coordination of training courses;
3. Oversight of joint / observed inspections;
4. Oversight of inspection system audits;
5. Dissemination of outputs and monitoring of uptake.

WORK CLUSTER UPDATES

The following pages provide a summary of the work carried out in each of the five work clusters in 2023.

2.2. WC 1 - Inspection guidelines

There was a change in the WC leader during 2023, with a member taking temporarily over that task until a new WC leader was identified. One of the key considerations for Work Cluster 1 was the requirement for a systematic review of existing guidance documents on inspections and inspections systems and, where necessary, the revision of such existing documents and the development of new guidance documents. From 2021 to 2023, specific sections of the inspection guidelines were revised, for some parts in cooperation with the Vigilance expert sub-group (VES).

The work was mostly focused on:

- (1) including an inspection report template;

- (2) reviewing the definitions on Critical/Major/Other deficiencies;
- (3) updating of the definition of “substantial changes” in the licence.

After collection of comments from IES members on the proposed revisions, the common EU SoHO Inspection Report Template (with classification of deficiencies) and the definition on substantial changes will be integrated into the Inspection guidelines in 2024.

2.3. WC 2 – Coordination of training courses

WC2 oversees the development and coordination of training courses on inspection as a tool to harmonise inspection methods across the EU and to improve the mutual recognition among MSs in the field of blood, tissues and cells.

WC2 team was actively working on the design and delivery of training courses (i.e. e-learning, residential face-to-face, practical experience) addressed to European inspectors, assessors and vigilance officers in the field of blood and blood components, tissues and cells and organs via the project SIGHTSoHO (strengthening overSIGHT through training and networking in the field of Substances of Human Origin <https://www.sightsoho.eu/>).

Weekly online trainings started at the end of **November 2023** and will end in early **March 2024**. After online trainings, 3 face to face workshops will be held in 2024 (Preparation Process Authorisation in May, Inspection in June, and Vigilance in July).

2.4. WC 3 – Coordination of Joint Inspections

The overall objective of WC3 is the coordination of inspection-related activities between competent authorities from different Member States, such as joint or observed inspections. The main working tools are the Deliverables of the VISTART joint action (WP8), which include the Code of Practice for Joint Inspections as well as the associated documents, such as inspection report forms, etc.

The Code of practice on joint inspections aims to establish a framework for joint inspections by multi-member states teams and to provide

assistance to inspectorates in organization and performance of joint inspections.

A new work cluster leader was designated during the IES meeting, and the cluster prepared a revised survey to be circulated to Competent Authorities for interest to participate in Joint Inspections (survey to be run early 2024).

2.5. WC 4 - Oversight of Inspection systems

The task of WC4 is oversight of inspection system, starting from “CESIP Audit Programme” developed as part of the VISTART joint action (WP9).

In 2021, the existing CESIP Audit documents were revised and updated but not finalised. There have been two changes of leaders for this WC during the period 2021-2023 and during the IES meeting (and afterwards), no new WC leader had been identified.

2.6. WC5 – Dissemination and Monitoring

The WC5 leader stepped down from the position in 2023, and a call was sent to all IES members to take on the role of leader, but no one expressed interest.

3. OTHER TOPICS

IES has collaborated with VES in previous years, and further collaboration is necessary, especially concerning WC1. Several meetings have been held between the IES and VES coordinators, and each sub-group presented its activities during the meeting of the other sub-group.

The work plan for 2024 will be finalised in January 2024, for approval by the IES in February.