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Competent authority viewpoint: **Experiences from the Inter-Member State audit (IES-WC4)**

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Federal Office for Safety in Health Care

Institute Surveillance - Department for Blood, Tissue and Vigilance

CNS, 28.03.2023

Organigramm AGES MEA/BASG

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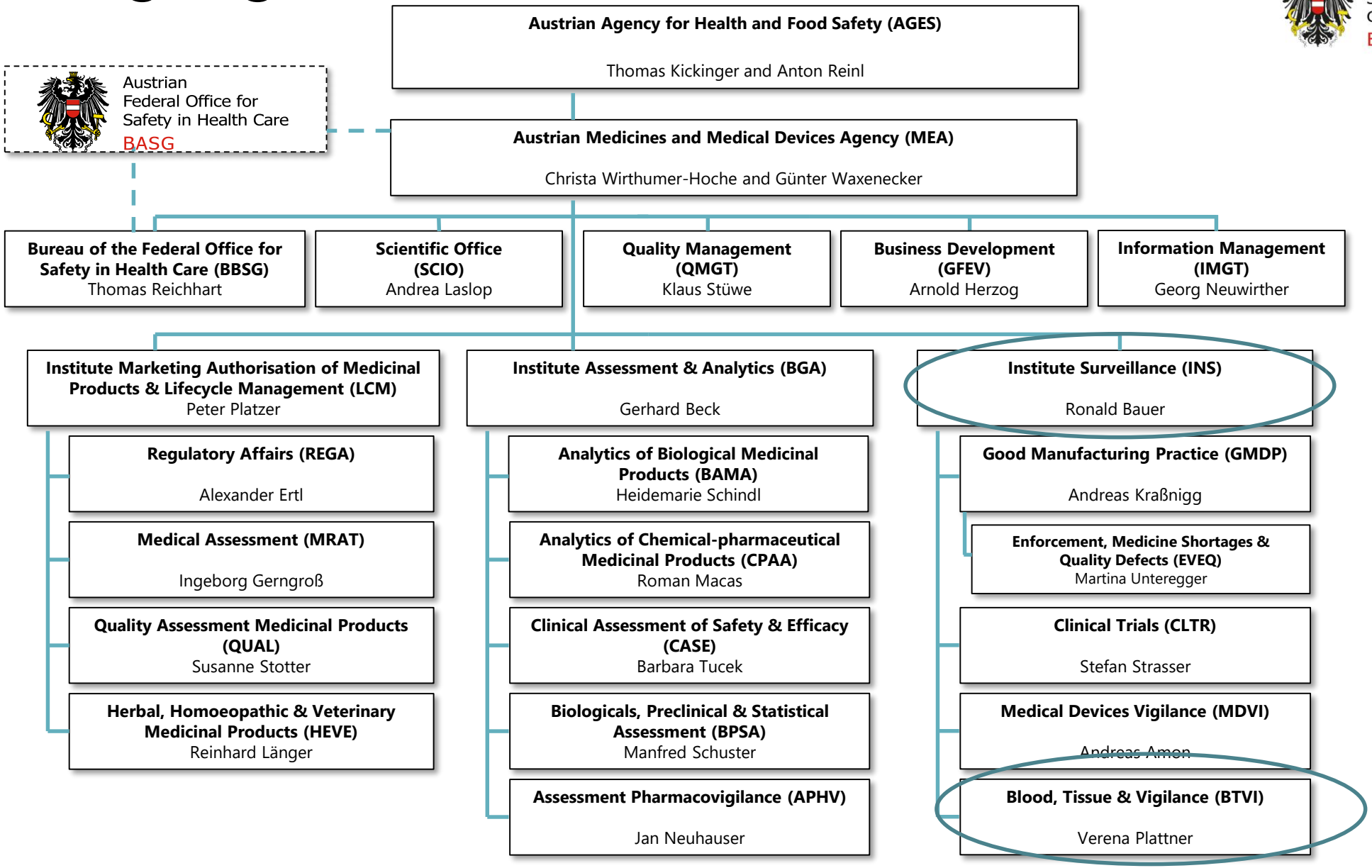

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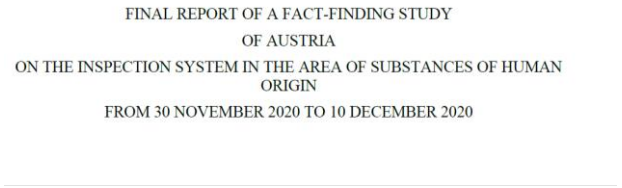
Agenda

- History

- Audit preparation

- Audit

- Audit report, Audit completion


FINAL REPORT OF A FACT-FINDING STUDY
OF AUSTRIA
ON THE INSPECTION SYSTEM IN THE AREA OF SUBSTANCES OF HUMAN ORIGIN
FROM 30 NOVEMBER 2020 TO 10 DECEMBER 2020

- CAPAs, lessons learnt, feedback

Inter-Member State audit

History

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within Framework of **VISTART** project (2015-2019):

WP 9: **A Voluntary Programme of Inter MS Inspection System Auditing**

- has been developed with the aim of validating the quality and inspection systems in place at CA/Inspectorates,
- while also providing an opportunity for sharing of experience
- thus increasing mutual confidence (thus facilitating blood, tissues and cell distribution between MS)
- and guarantee citizens who travel across MS an equivalent level of regulation of these services;

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History

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CESIP (Common European SoHO inspection Programme)

was developed based on established audit programmes in the field of pharmaceutical inspection, including:

- the EU Joint Audit Programme (JAP),
- Pharmaceutical Inspectorate Co-operation Scheme (PIC/S)
- Benchmarking of European Medicines Agencies (BEMA) systems.

Training opportunity in Sept. 2018 for inspectors to act as CESIP Auditors!

Inter-Member State audit

History

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Deliverables:

CESIP Manual with

- Annex 1: CESIP Application and Pre-Audit Preparation;
- Annex 2: CESIP Audit Procedure;
- Annex 3: CESIP Audit Plan;
- Annex 4: CESIP Audit Checklist;
- Annex 5: CESIP Audit Indicator Interpretation Guide;
- Annex 6: CESIP Observed Inspection Procedure;
- Annex 7: CESIP Observed Inspection Checklist;
- Annex 8: CESIP Audit Report and Cover Letter

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History

The Commission **Expert Sub-Group on Inspections** in the Blood and Tissues & Cells Sectors (IES) is an

- active sub-group of the Competent Authorities on Substances of Human Origin (CASoHO) Expert Group
- established in late 2018
- 45 nominated representatives from 28 competent authorities

- The *primary objectives*
  - to provide technical expertise and formulate advice
  - comment to the Commission's services, and represent a forum for the exchange of information and
  - experiences between the different Member States on technical and procedural matters related to their national inspection programmes in the blood and tissues and cells sectors.

Inter-Member State audit

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History

- The *overall aim* is to
  - encourage further mutual recognition of inspections in the blood, tissues and cells sectors across the EU Member States and
  - provide a platform for EU-level collaboration on such activities.

Source: https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/ies_en.pdf

- *Organization* – different Work Clusters

IV.	**Oversight of inspection systems**	The goal of this work cluster will be the wider promotion of the CESIP audit programme, which is comparable to the existing Joint Audit Programme for GMP, but has a voluntary basis status. In the CESIP audit programme the quality management systems and inspections practices of the National Competent Authorities are to be evaluated on the basis of documents prepared by the VISTART Joint Action, which have been adapted and improved by the IES. To reduce the financial aspects for the auditees the possibility of support through the Commission's Structural Reform Support Service is being investigated.

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Audit preparation

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Formal application (october 2020)

CESIP Application Form

a) Contact Details for the Applicant:

1. Applicant: (Name of NCA / Inspectorate)
BASG / AGES MEA (Federal Office for Safety in Health Care)
2. Address:
Traisengg. 5/ 1200 VIENNA
3. Country:
AUSTRIA
4. Phone:

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Audit preparation

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Formal announcement of a SoHO fact finding mission (November 2020)

Via **European Commission**
Directorate – General for Health and Food Safety
Directorate F – Health and food audits and analysis
Unit F5 Health Protection

- Letter to CEO
- Fact finding mission plan

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Audit preparation

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Self-evaluation regarding the CESIP indicators (incl. supporting documents)

ANNEX – **2020-7310 SoHo AT self-evaluation**

Glossary:

AGES	Agentur für Gesundheit und Ernährungssicherheit	Austrian Agency for Health and Food Safety
AGES MEA	AGES Medizinmarktaufsicht	Austrian Medicines and Medical Devices Agency
BASG	Bundesamt für Sicherheit im Gesundheitswesen	Federal Office for Safety in Health Care
BSG	Blutsicherheitsgesetz	Austrian Blood Safety Act
GESG	Gesundheits- und Ernährungssicherheitsgesetz	Austrian Health and Food Safety Act
GSG	Gewebesicherheitsgesetz	Austrian Tissue Safety Act
IVF-Fonds-G	IVF-Fonds-Gesetz	Austrian In Vitro Fertilisation Act
SVA	Standardverfahrensanweisung	SOP

Component 1 - Legislative and Regulatory Requirements

General comment: BASG is the Austrian National Competent Authority as identified in matter legislation regarding medicines, medical devices, blood and tissues. According to the Austrian Health and Food Safety Act (GESG), all operative activities of BASG are performed by AGES MEA, which is a division of AGES, on behalf of BASG. AGES is a company ltd. 100% owned by the Republic of Austria. Most services of AGES are performed on behalf of national or regional authorities, but AGES may also involve in commercial contracts. However, according to GESG § 8 (7) the division AGES MEA is not allowed to engage in any activities under the authority of BASG on behalf of third parties (https://www.basg.gv.at/en/about-us).

Subcomponent	Indicators	Self-evaluation	Supporting information
1.A Empowering legislation	1.A.1 Legal provisions exist that provide a mandate the NCA / Inspectorate to perform activities relating to inspection Including; a) the organisation of inspections; b) the designation and empowerment of inspectors;	The legal provisions that provide a mandate to perform inspections on **blood** establishments are set up on BSG § 14 (manufacturing authorisation) and § 15 (4) (access to premises and documentation).	• Link to BSG

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Audit preparation

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4.A Inspection Procedures	**4.A.1 A system for the scheduling of inspections is defined, documented and implemented;**	**System in place**	**SVA_I20 Planung und Zuteilung von GMDP-/BSG/AMG,GSG-Inspektionen (Planning and allocation of GMP/GDP, blood and tissue inspections) SVA_I19 Risikoklassifizierung von Betrieben und deren Konsequenz (risk based inspection plannning)**
	4.A.2 A system for the planning and preparation of inspections is defined, documented and implemented;	System in place	SVA_I20 Planung und Zuteilung von GMDP-/BSG/AMG,GSG-Inspektionen (Planning and allocation of GMP/GDP, blood and tissue inspections) SVA_V39 Inspektionen und QRBE durchführen (performing inspections and Quality Risk Based Evaluations chapter 2+3)

Inter-Member State audit

Audit preparation

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Draft agenda

	WEEK
Day 1. Monday 30 November. 9:00-10:45	**Day 2. Tuesday 1 December. 9:00-10:45**
-Initial meeting introductions - Brief explanations by AGES of the activities that the BTVI carries out -Inspectors recruitment process.	- Organisation of training for SoHo inspectors - Inspector qualifications process. - Maintenance of inspectors' competence and performance evaluation
Day 1. Monday 30 November. 11:15-12:45	**Day 2. Tuesday 1 December. 11:15-12:45**
-Designation and powers of inspectors -SoHo inspectors' job descriptions -Enforcement powers	- Continuation of previous session

Inter-Member State audit

Audit

Study team	Two auditors and two observers from the European Commission and five national experts from the following authorities: • Federal Agency for Medicines and Health Products, Belgium • Ministry of Health, Croatia. • Istituto Superiore di Sanità, Italy • Health and Youth Care Inspectorate, the Netherlands
Study dates	30 November to 10 December 2020

Inter-Member State audit

Audit

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CESIP Audits involve 3 different methods for evaluating and verifying information, including;

- Documentation Review (DR): a review that relevant documents and procedures are in place and are appropriately detailed;

- Evaluation at NCA / Inspectorate (EI); a verification of procedures and systems in place through sources at the NCA / Inspectorate, such as discussions with relevant staff and verification of other relevant documentation (i.e. records, logs, meeting minutes etc.)

- Observed Inspection (OI); where the CESIP audit team observes an inspection being performed by the auditee. Note: this is not a joint inspection. An observed inspection is primarily used by the auditor to evaluate the system and methods used by the Auditee on inspections.

Inter-Member State audit

Audit

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Opening meeting

Collecting Information/Evaluating and Verifying Information

Component 1: Legislative and Regulatory Requirements

mandate to perform activities relating to inspection, including the organisation of inspections and the designation and empowerment of inspectors

Component 2: Governance and Organisation

organisation and structure of BASG/AGES MEA, workflow organisation, staff roles and job descriptions, planning and implementation of internal communication

Inter-Member State audit

Audit

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Component 3: Quality Management System

QMS, Risk management, KPIs, document control and access rights, management review, internal audits

Component 4: Inspection System

Planning and scheduling of inspections: timeline, method, deciding the inspection team composition, frequency of inspections,

Closing meeting

Main findings and conclusions were presented

Inter-Member State audit

Audit report, Audit completion

Bundesamt für Sicherheit im Gesundheitswesen
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Draft report (january 2021)

Excerpt of the CESIP Manual:

- The Auditee sends its response indicating whether they acknowledge and accept the observations and conclusions of the CESIP audit.
- Comments regarding the factual accuracy of the report may also be submitted by the Auditee if required with their response.
- If required, the team leader can include the Auditee comments to into an amended audit report, which is sent to the Auditee.

Inter-Member State audit

Audit report, Audit completion

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No	Ref	Issue	Action ID	Action	Planned te	Status
Obs. 1	2.B.5	There is no periodical renewal of the confidentiality agreement that staff must sign when they join AGES.	QM-report KSTE-BYAC8F	Form F_I345 for preparation of annual appraisal interviews of inspectors will be amended to include the required confidentiality statement.	16.02.2021	Done

4. Verschwiegenheitsverpflichtung

☐ Ich bestätige die durch meinen Dienstvertrag festgelegte Verpflichtung zur Verschwiegenheit.

Datum, Unterschrift Mitarbeiter	Datum, Unterschrift Führungskraft

Das ausgefüllte unterschriebene Formular ist im Original im Personalordner abzulegen.

F INS VIE 00QM I345 05 Gültig ab: 16.02.2021 2 von 2

Inter-Member State audit

Audit report, Audit completion

Bundesamt für Sicherheit im Gesundheitswesen
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Audit completion with letter to CEO including final report (february 2021)

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and food audits and analysis

DG(SANTE) 2020-7310

FINAL REPORT OF A FACT-FINDING STUDY

OF AUSTRIA

ON THE INSPECTION SYSTEM IN THE AREA OF SUBSTANCES OF HUMAN ORIGIN

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CAPAs, lessons learnt, feedback

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CAPA

Observations (Obs.) and Observations for potential improvements (OFI) were included in the quality management system (tracking via the in-house Quality management notifications tool), if applicable.

		needs.	are identified on the job, in department meetings and annual appraisal interviews.			
OFI 3		The preparation of inspections could be speeded up if the preparatory work is done electronically and included in the report template, instead of doing it manually on a separate piece of paper.	change request IGMDP 2666	Submission of change request for PHAROS to include recommended duration and number of inspectors for the next inspection	03.02.2020	Done (implementation will be followed by IT project log)

Inter-Member State audit

CAPAs, lessons learnt, feedback

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Organisation

- Good structure and clear comunication in the preparation process
- Practical to have some information about the NCA already in English (Organizational chart, basic information, etc.)

Work load

Time consuming (support by our QM-team)

- Self evaluation
- Compiling documents
- Translating documents (recommendation: www.deepl.com)

Inter-Member State audit

CAPAs, lessons learnt, feedback

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Remote Audit

Worked very well:

- clear structure
- Clear ways of communication

Thanks to the very good preparation by the audit team and good discipline during the meeting!

A remote audit, however, might be more difficult if a NCA is working mainly paper-based.

Inter-Member State audit

CAPAs, lessons learnt, feedback

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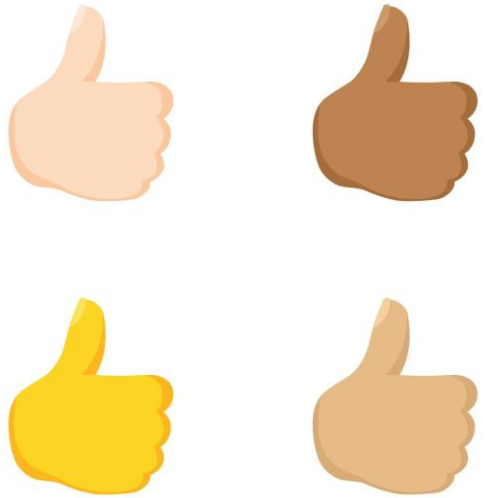
Experience

- Very valuable tool for benchmarking
- Good chance for improvement → look from the outside (not operationally blind)
- Promoting transparency to the public stakeholders
- Harmonizing on EU-Level



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BASG

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