

Competent authority viewpoint:

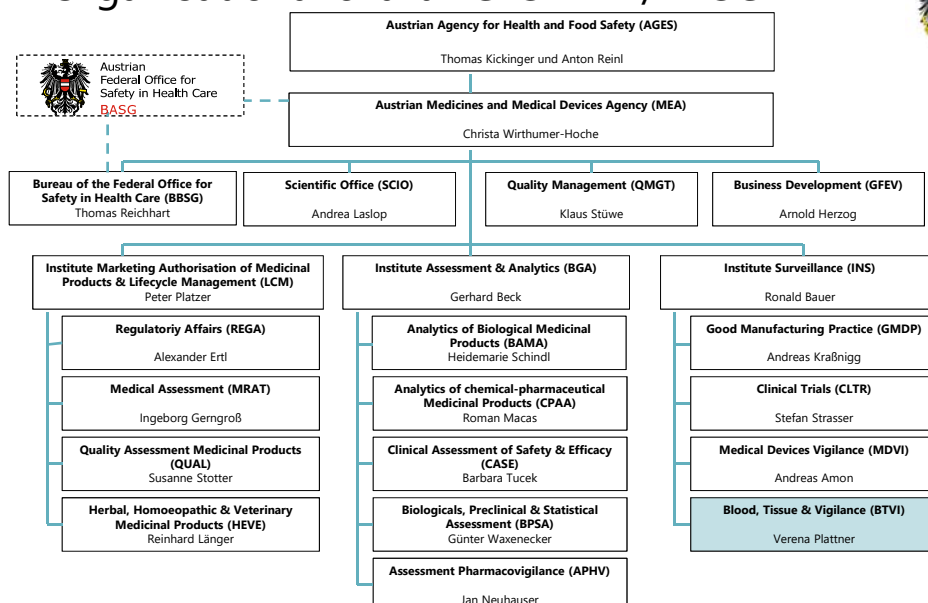
Experience and lessons learnt from the COVID-19 pandemic

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Organisational chart AGES MEA/BASG



L_MEA_SGB_00QM_A04_26

valid from: 12.07.2019

2

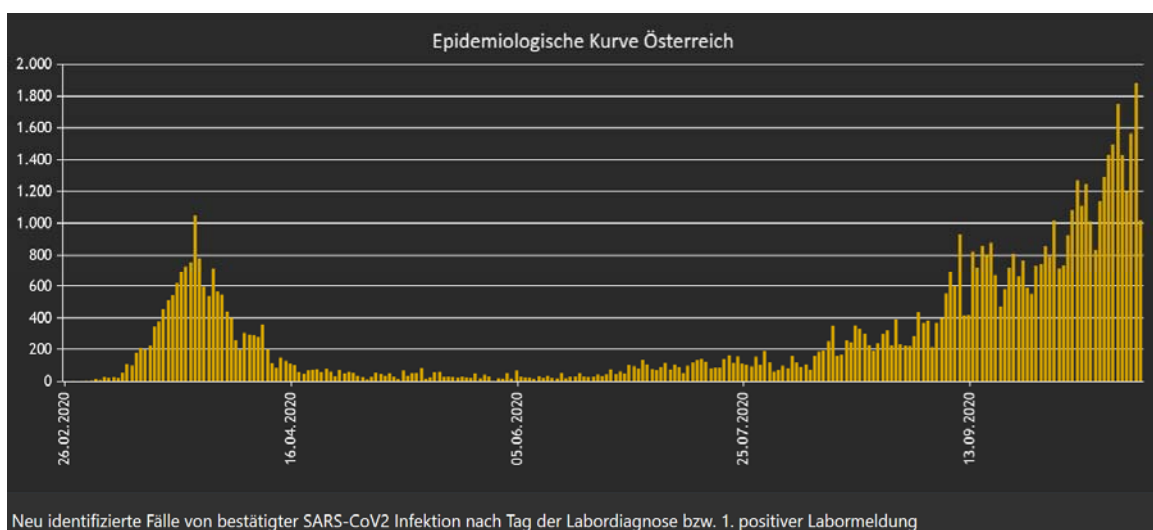
Covid Agenda

- **Impact on the regulatory functions** in the field of blood (inspection, authorisation and haemovigilance)
- **Lessons learnt** and changes to ensure that quality and safety was maintained
- Work of the **inspection expert subgroup** (IES)

3

Impact on the regulatory functions

Pandemic situation in Austria



Source: <https://covid19-dashboard.ages.at/>

4

Impact on the regulatory functions

Pandemic situation in Austria, preventive measures (23.10.2020)

Public areas, events, private meetings

- Wearing of face masks in public areas, public transport, and at events indoor and outdoor
- No catering at events
- Privat sector: 6 persons indoor, 12 outdoor

Restaurants

- Not more than 6 persons on a table
- Restaurants with more than 50 seating capacities need specific preventive concepts

Health sector

- Face masks in general areas
- Regular tests for personnel

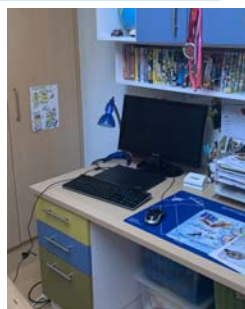
5

Impact on the regulatory functions

BASG/AGES MEA

Organizational changes

beginning with the
lockdown – business
continuity:



- Immediate start of home office for employees equipped with laptops
- Organization of laptops and home connections for other personnel within the following two weeks
- Change to online meetings
- Organization of training courses for online tools
- Psychological guidance

6

Impact on the regulatory functions

Haemovigilance

Operative changes

- No impact on process itself

SARS-CoV2- related tasks

- **Rapid circulation of informations** such as epidemiological issues to Austrian blood establishments and vice versa (Rapid Alerts, Information von ECDC, EC, national Signals, etc)



Impact on the regulatory functions

Haemovigilance

SARS-CoV2- related tasks

- *At the beginning: collaboration with the Ministry of Health and the ÖGBT (Austrian Society for Blood Group Serology and Transfusion Medicine) to define regions where blood collection could still performed*
- *Publication of informations from the EC/ECDC*
- *Ongoing: publication of Risk Assessments of ECDC*
- **Interface to clinical trials:** training of colleagues which assess SUSARs (suspected unexpected serious adverse reactions) to forward these informations also to the Haemovigilance Department

Impact on the regulatory functions

Blood inspections

Operative changes

- **No on site inspections** since mid of March until reopening in May
- Immediate **change to remote** (mainly paper based) inspections
- After lock-down on site inspections started again:
 - *Communication of preventive measures requested from BASG/AGES MEA*
 - *Communication of preventive measures requested from the inspectees*
 - Goal: reach a consensus 😊
- **Currently both:** on site and remote (depending on internal RA, focus of inspection, ..)

➡ No reduction in the routine inspection programme because of COVID-19 expected

9

Impact on the regulatory functions

Blood inspections

SARS-CoV2- related tasks:

- **Classification of COVID-19 convalescent plasma** in AT at the end of March
 - no specific Covid-19 authorization needed
 - but authorization inspections in case of changes, e.g. new process of collecting plasma via apheresis, new apheresis systems, ...
 - later reference to the Commission Homepage, relevant COVID-9 documents and EU CCP Database
- **Collaboration with the EC** in case of regulatory topics related to Covid-19-Plasma

10

Lessons learnt

Confusion about keeping open

- Discussion of **temporary closure** of blood establishments/plasma centers
 - Voluntary closure because of unavailability of protective equipment
 - Some closures because of unclear legal situation
 - Closure of public buildings – mobile blood donor campaigns could not be performed

Question was raised if it was/is allowed to keep open during lock-down?

→ no legal requirements to close establishments (legal exemption)
but clarifying remarks were circulated from Ministry of Health

11

Lessons learnt

Collaboration with EC/ECDC



- very supportive
- very prompt
- right topics at right time

12

Expert Sub-Group on Inspections (IES)



- 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.

13

Expert Sub-Group on Inspections (IES)



- 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

14

Expert Sub-Group on Inspections (IES)

Inspections during lockdown



Different approaches within the EU Member States (Tour de table before summer)

- No site inspections since lock-downs
- Beginning of planning of desk based inspections
- Short vs big delays in programme (question of flexibility in legal framework)
- Remote and on site in parallel
- ...

15

Expert Sub-Group on Inspections (IES)

Remote Inspections



IES is **organised via Work Clusters** (WC1-WC5) dealing with different topics such as harmonised documents, inspection procedures, harmonised training, ...

➡ Work Cluster (WC) 1: focus on harmonising existing guidelines
based on the current pandemic situation a document for remote inspections will be developed as part of WC 1

Additional input on the last NCA Meeting Blood and Blood Components (15.10.2020):
EMA has set up a drafting group to develop further guidance related to distant assessments for GMP/GDP and PMF inspections

16

Expert Sub-Group on Inspections (IES)

Remote Inspections



Topics to cover:

- the communication processes between the different teams
- possibilities for teleconference/videoconference
- access to inspectors to computerised systems
- platforms with an adequate standard of security to share documents, ...
- transfer of information of large electronic documents

17

